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EVALUATION OF THE

SELF -HELP INTERVENTIONS PROGRAM (SHIP): PSYCHOEDUCATIONAL

INTERVENTIONS FOR

PATIENTS WITH BREAST CANCER

by

Diep Ngoc Duong

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A Dissertation Submitted to the Faculty of the

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entitled Evaluation of the Self-Help Interventions Program: Psychoeducational Interventions for Patients with Breast Cancer

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STATEMENT BY THE AUTHOR

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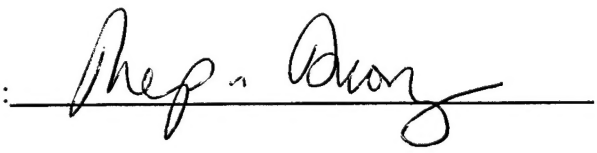
SIGNED: 

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TABLE OF CONTENTS

PAGE

LIST OF ILLUSTRATIONS 8
LIST OF TABLES 10
ABSTRACT 12

CHAPTER I. INTRODUCTION 14
Definition of Terms 21
Statement of the Problem 23
Statement of Purpose 23
Background of the Problem 24
Breast Cancer: Incidence, Risk Factors, Diagnosis, and Treatment 24
Breast Cancer and Its Impact 26
Supportive Care Services 27
Psychological and Educational Interventions as Supportive Care 28
Lack of Strong Clinical Trials 29
Lack of Specificity in the Components of Interventions 30
SHIP: A Psychoeducational Intervention - A Test of Multi-Components Intervention 31
Significance of the Study 32
Summary 35

CHAPTER II. THEORETICAL FRAMEWORK 37
Overview of the Framework 37
Derivation of Treatment Framework 37
Substantive Theory 37
Treatment Theory 41
Treatment Framework of the SHIP Intervention 42
Conditioning Category 43
Intervention Category 45
Proximal Outcomes Category 46
Distal Outcome Category 50
Theoretical Assumptions 51
Major Propositions of the Framework, Variables Included, and Definitions of Included Variables 52
Conditioning Category 52
Intervention Category 55
Proximal Outcomes Category 59

TABLE OF CONTENTS —*Continued*

PAGE

Distal Outcome Category 60
Review of the Literature 61
The Cancer Experience 61
Conditioning Category 64
Intervention Category 78
Proximal Outcomes Category 85
Distal Outcome Category 87
Summary 89

CHAPTER III. METHODOLOGY 91
Research Design 91
Criteria for Inclusion 91
Human Subjects' Protection 93
Sample and Setting 94
Instrumentation 97
Conditioning Variables 97
Intervention Variables 100
Proximal Outcomes Variables 110
Distal Outcome Variable 113
Data Collection Procedure 115
Specific Hypotheses to be Tested 119
Conditioning Variables 119
Intervention Variables 123
Proximal Outcomes Variables 126
Data Analysis Plan 127
Limitations of the Study 135
Summary 136

CHAPTER IV. RESULTS 137
Description of the Sample 138
Personal Characteristics 139
Medical Characteristics 140
Support Characteristics 141
Preparation of Data 142
Assessment of Instruments 144
Examination of Missing Data 148
Quantification of Treatment Strength 150

TABLE OF CONTENTS —*Continued*

PAGE

The Self-Help Independent Study (SHIS) Group 153
The Self-Help Class (SHC) Group 157
The Uncertainty Management (UM) Group 161
The SHIS Plus UM Group 163
The SHC Plus UM Group 166
The Natural Learning Condition (NLC)/Control Group 169
Change Rate and Change Pattern 171
Hypotheses Testing 200
GROUP 'A' 203
GROUP 'B' 213
GROUP 'C' 221
Summary 231

CHAPTER V. INTERPRETATION, RECOMMENDATIONS, AND IMPLICATIONS 239
Interpretation 239
Recommendations 257
Implications 262
Summary 264

APPENDIX A: Human Subjects Approval of the SHIP Project 267
APPENDIX B: Human Subjects Approval of the Evaluation of the Self-Help Intervention Project: Psychoeducational Interventions for Women with Breast Cancer 279
APPENDIX C: Instruments Used in This Study 281
APPENDIX D: Quantification of SHIP Treatment 316
APPENDIX E: Sample of SAS Program for Individual Growth Curve AnalysisStatistical Analyses Sample of SAS Program for Plotting Growth Curves 319
APPENDIX F: Plottings of Individual Change per Outcome Variable by Treatment Groups 332
REFERENCES: 378

LIST OF ILLUSTRATIONS

FIGURES **PAGE**

Figure 2.1 Self-Help Model 40
Figure 2.2 Treatment Framework 44
Figure 2.3 Illustration of Treatment Effect and Change Process 49
Figure 2.4 Research Variables Included in the Conditioning Category and Its Propositions 53
Figure 2.5 Research Variables Included in the Intervention Category and Its Propositions 56
Figure 3.1 Research Design 92
Figure 3.2 Sampling Process of the Self-Help Intervention Project (SHIP) 96
Figure 3.3 Data Collection Points and Attrition Rate of the Self-Help Intervention Project (SHIP) 116
Figure 3.4 Proposed Hypotheses Related to Conditioning Factors to be Tested 120
Figure 3.5 Proposed Hypotheses Related to Intervention, Proximal, and Distal Outcomes to be Tested 124
Figure 3.6 Data Analysis Plan 130
Figure 4.1a Mean Change on 'Belief in Self' for All Treatment Groups 176
Figure 4.1b Mean Change on 'Cognitive Reframing' for All Treatment Groups 177
Figure 4.1c Mean Change on 'Problem Solving' for All Treatment Groups 178
Figure 4.1d Mean Change on 'Self-Help' for All Treatment Groups 181
Figure 4.1e Mean Change on 'Uncertainty' for All Treatment Groups 182
Figure 4.1f Mean Change on 'Psychological adjustment' for All Treatment Groups 183
Figure 4.1g Mean Change on 'Well-Being' for All Treatment Groups 184
Figure 4.2 Statistically Significant Relationships Among SHIS Treatment, Proximal Outcomes, and Distal Outcome 188
Figure 4.3 Statistically Significant Relationships Among SHC Treatment, Proximal Outcomes, and Distal Outcome 190
Figure 4.4 Statistically Significant Relationships Among SHIS/UM Treatment, Proximal Outcomes, and Distal Outcome 194
Figure 4.5 Statistically Significant Relationships Among SHC/UM Treatment, Proximal Outcomes, and Distal Outcome 198
Figure 4.6 Statistically Significant Relationships Among 'Usual' Treatment Level, Proximal Outcomes, and Distal Outcome in the Natural Learning Condition/Control Group 201

LIST OF ILLUSTRATIONS —*Continued*

FIGURES **PAGE**

Figure 4.7 Significant Findings of Relationships Among Conditioning Factors, Levels of SHIS/UM or SHC/UM Treatment, Proximal Outcomes, and Distal Outcome 212
Figure 4.8 Significant Findings of Relationships Among Conditioning Factors, Levels of UM Treatment, Proximal Outcomes, and Distal Outcome 222
Figure 4.9 Significant Findings of Relationships Among Conditioning Factors, Levels of SHIS or SHC Treatment, Proximal Outcomes, and Distal Outcome 230

LIST OF TABLES

TABLES **PAGE**

Table 1.1 Supportive Services Clinical Trials in Cancer Patients 19
Table 1.2 Definitions of Term Being Used in This Study 22
Table 3.1 Group Assignment and Subjects per Group/Cell 95
Table 3.2 Instrumentation for Conditioning Variables 99
Table 3.3 Indicators of Strength of the Independent/Intervention Variable: SHIP Intervention and Its Components 103
Table 3.4 Self-Help Independent Study and Self-Help Class Protocol 105
Table 3.5 Instrumentation for Proximal Outcome Variables 113
Table 3.6 Instrumentation for Distal Outcome Variable 114
Table 4.1 Support Characteristics of the Typical Patient 143
Table 4.2 Assessment of Measures: Reliability - Standardized Item Alpha for Measures Over All Data Points 145
Table 4.3 'Missing' Factor as a Predictor of Outcomes 150
Table 4.4 Sample Distribution in the SHIP Intervention Groups 151
Table 4.5 Overall Treatment Strength for Each Treatment Group 153
Table 4.6 Treatment Strength of the Self-Help Independent155 Study (SHIS) Component of the SHIP 155
Table 4.7 Treatment Strength of the Self-Help Class (SHC) Component of the SHIP 160
Table 4.8 Treatment Strength of the Uncertainty Management (UM) Component of the SHIP 164
Table 4.9 Treatment Strength of the Combined Self-Help Independent Study (SHIS) and the Uncertainty Management (UM) Component of the SHIP 167
Table 4.10 Treatment Strength of the Combined Self-Help Class (SHC) and the Uncertainty Management (UM) Component of the SHIP 170
Table 4.11 Treatment Strength of the Natural Learning Condition (NLC)/ Control Group 171
Table 4.12 Summary of Change Rate and Change Patterns for All Groups on Proximal and Distal Outcomes 174
Table 4.13 Change Pattern and Change Rate in Proximal and Distal Outcomes for the SHIS Group 185
Table 4.14 Change Pattern and Change Rate in Proximal and Distal Outcomes for the SHC Group 189

LIST OF TABLES —*Continued*

TABLES **PAGE**

Table 4.15 Change Pattern and Change Rate in Proximal and Distal Outcomes for the UM Group 191
Table 4.16 Change Pattern and Change Rate in Proximal and Distal Outcomes for the SHIS/UM Group 193
Table 4.17 Change Pattern and Change Rate in Proximal and Distal Outcomes for the SHC/UM Group 196
Table 4.18 Change Pattern and Change Rate in Proximal and Distal Outcomes of the Natural Learning Condition/Control Group 199
Table 4.19 Summary of Change in Proximal outcomes for GROUP 'A' and the NLC/Control Group 208
Table 4.20 Summary of Change in 'Well-Being' for GROUP 'A' and the NLC/Control Group 209
Table 4.21 Summary of Change in 'Uncertainty' for GROUP 'B' and the NLC/Control Group 217
Table 4.22 Summary of Change in 'Psychological Adjustment' for GROUP 'B' and the NLC/Control Group 218
Table 4.23 Summary of Change in 'Well-Being' for GROUP 'B' and the NLC/Control Group 219
Table 4.24 Summary of Change in Proximal outcomes for GROUP 'C' and the NLC/Control Group 226
Table 4.25 Summary of Change in 'Well-Being' for GROUP 'C' and the NLC/Control Group 227
Table 4.26 The Effects of Treatment on Change of Well-Being by the Treatment Groups 233
Table 4.27 Change Rate in Outcomes by GROUP 'A', "B', and 'C' 234

ABSTRACT

The purpose of this study was to further develop treatment theory for SHIP psychoeducational interventions in order: 1) to discover those interventions which proved to contribute toward significant change rate in the self-reported perceptions of breast cancer patients concerning their feelings of personal 'well-being', 2) to assess the stability of the SHIP's treatment effect during the follow-up data collection period, 3) to profile which individuals were most likely to benefit from specific components of SHIP interventions, and 4) to test the processes by which the SHIP interventions affected the outcome. Outcomes studied were change in: self-help, enabling skills (belief-in-self, cognitive reframing, & problem solving), uncertainty level, psychological adjustment, and 'well-being'. Profiling factors were personal characteristics, medical characteristics, baseline support level, and baseline mastery level.

Data were derived from the Self-Help Interventions Project (SHIP), an experimental, longitudinal study which had provided psychoeducational interventions to women with breast cancer in order to help them cope with their situation. The SHIP interventions consisted of education and psychological components. A nonprobability sample of 307 women was randomized into one of five possible treatment groups and a natural learning condition/control group.

Study results revealed that, in general, change patterns in outcomes were as expected, though magnitude of change rates was modest to moderate. Significant impact was

strongest for those who participated in: the Self-Help Independent Study plus Uncertainty Managment combined intervention, and the Self-Help Independent Study intervention.

Recommendations include: 1) re-examine intervenors' characteristics through further secondary data analysis of the SHIP study; 2) replicate part of this study using only the stronger components such as the combined Self-Help Independent Study/Uncertainy Management groups, and the individual Self-Help control group in a more homogeneous and larger sample size; 3) use alternative methods of measurement to capture the changes in outcomes. For example, measure functional status through the categories of 'performing self-care', and 'returning to school/work/hobby'; and 4) measure more frequently in order to determine the possibility of using "booster" lessons.

CHAPTER I

INTRODUCTION

Some 20 plus years ago few had the heart to talk about cancer. Breast cancer transforms a woman's breast into a vehicle of death. This disease in the past was synonymous with death. Medical therapies for the disease were nightmares of pain, disfigurement, and uncertainty.

The story of a typical female breast cancer victim goes something like this per (Hagopian, 1993; Hilton, 1988; Ireland, 1987; Kushner, 1982; and Moch, 1990; 1995). Eileen, a seemingly healthy, 45 year old employed woman had nothing more than a tiny lump (which she had discovered accidentally) in her breast. Days passed before she could see a physician. While waiting, routines and chores went on as usual, but Eileen was constantly reminded of "the lump". Was it cancer? Perhaps it was only a lump?

Uncertainty prevailed while she was awaiting confirmation. Days later came the biopsy. She was told by her doctor that it was cancer. She felt a flame of fear deep in her gut. Decisions...decisions of what to do next. When to have surgery? Which type of surgery to undergo? To have chemotherapy or not? Whom to consult? So many other major issues would need to be dealt with; however, she was almost exclusively focused on "the lump". She contemplated why she had gotten this affliction. She wondered if she had done something wrong.

Soon came the surgery followed by more waiting. She waited for the pathology report in order to determine the extent of her disease. Although the physical discomfort was great, Eileen was more worried about how she would appear after the bandages came off and the tubes and drains had been removed; and she worried how others would respond to her in her altered physical state.

When the pathology report finally came, it declared there were "eight positive nodes"; that meant she would have to endure chemotherapy. She felt angry, victimized, fearful, and trapped. Chemotherapy is employed when the cancer is not under control....dying was now no longer a remote possibility for Eileen. Death was no longer a remote theoretical concept. It now became quite personal and of immediate concern. As if the uncertainties of cancer were not enough, therapy added an even greater sense of losing control over one's own life. Chemotherapy also meant being sick, losing hair, and being unable to work. For Eileen it seemed that losing her hair was worse than losing her breast.

She felt compelled to learn as much as she could about the chemotherapy she was to endure. Chemotherapy was not easy for her; she became so ill from it that she was unable to continue her career. She was miserable the whole day; she felt as if her body were on fire. She had fever and chills at five-minute intervals all day and night. She had dreadful pain in her ovary area. She felt tired most of the time; everything in her life revolved around the chemotherapy. She felt defeated and helpless. She knew that the

course of breast cancer is unpredictable, and that the outcome of therapies for breast cancer are uncertain.

Each day was a new day for Eileen. She came to realize that it was important for her to be more informed so she could make decisions based on clear thinking. She sought support available in the local community, but that support was limited to cancer support groups. She felt lonely and frustrated. People are there, friends call, husband and family members cry, and co-workers voice concern. But in the middle of the night, when the possibility of death absorbed her, Eileen felt she was alone. How she wished she had someone to talk who currently had the disease, or who had experienced it. She wondered how others had gotten through the experience or were now dealing with their breast cancer.

As she thought about herself and her illness, she also realized that she would take any opportunity to beat the disease and sustain her lifestyle. It seems as if always there was a next step; and along with the next step came more uncertainty. Although her regular check-ups were "normal", Eileen thought "you are never home free from breast cancer, Never!" Eileen felt "stopped" and "cheated" by her diagnosis of breast cancer (Hagopian, 1993; Hilton, 1988; Ireland, 1987; Kushner, 1982; Moch, 1990; 1995).

Cancer of the breast is the most common major cancer experienced by women in the United States; it accounts for 29% of all cancers experienced by those women. Topics related to breast cancer are frequently mentioned and discussed in various

professional disciplines, as well as in lay magazines and the media. Breast cancer was propelled to the "headlines" when high profile women were diagnosed with breast cancer, reinforcing the "vulnerability" aspect of this disease (Ireland, 1987).

The impact of a breast cancer diagnosis and its subsequent treatment is a major turning point in women's lives, as in Eileen's life. These women are most vulnerable to distress immediately after diagnosis, and that distress continues for two to three months into the illness (Weisman & Worden, 1976-77). Women who are diagnosed with breast cancer encounter many uncertainties which influence how they adjust and adapt to everyday life experiences (Frank-Stromborg, Wright, Segalla & Diekmann, 1984; Freidenbergs, Gordon, Hibbard, et al., 1981-1982; Lasry, Margolese, et al., 1987). When a woman is informed that she has breast cancer, she is faced with physiological imbalance (Knobf, 1986; Wallis, 1991), psychosocial distress (Christman, 1990; Frank-Stromborg, et al., 1984), uncertainties (Brandt, 1987; Christman, 1990; Mishel, Hostetter, King & Graham, 1984), social isolation (Spiegel, 1990), and sudden termination of her customary life-style (Munkres, Oberst & Hughes, 1992).

Supportive care services, which are currently inadequately funded and insufficiently available, aim to maintain the positive quality of patients' lives, and compliment medical treatments for breast cancer. The emphasis is on positive quality of survival, as exemplified in Eileen's case, rather than mere survival. Supportive care

services aim to assist patients in dealing with emotional, physical, and practical difficulties following diagnosis and treatment of cancer (Spiegel, 1990).

Reports of clinical trials related to supportive care services (specifically psychosocial educational programs) for persons with chronic illnesses are recent additions to the health-care literature. There are over 100 studies of psychosocial support service effectiveness for cancer patients in the literature. Table 1.1 provides a list of these studies organized by major foci. Overall, several themes are evidenced in reported clinical trials. When the disease is in stage I (cancer is localized) and recovery proceeds unimpaired, the severe distress related to cancer diagnosis dissipates, and adjustment stabilizes within one year after implemented medical therapies (Capone, Good, Westie & Jacobsen, 1980; Fawzy, Cousins, Fawzy, Kemeny, Elashoff & Morton, 1990; Houts, Whitney, and Mortel & Bartholomew, 1986). Outcome effects from individual counseling and behavioral interventions are stronger in patients with cancer in stage II or higher (patients are at higher risk for metastasis and/or recurrence). Interventions with components such as 1) offering information (d= .74); 2) teaching cognitive coping strategies (d= .59); and 3) combined education and behavioral categories (d= .46) are effective (Devine & Westlake, 1995). Similarly, Meyer and Mark's (1995) meta analysis of 45 psychosocial intervention studies found cumulative evidence for treatment effectiveness by enhancing emotional adjustment (d=.24), functional adjustment (d=.19), and symptoms management (d=.26).

Table 1.1 Supportive Services Clinical Trials in Cancer Patients

APPROACH	STUDY	INTERVENTION
Behavioral	Edgar, Rosberger & Nowlis (1992)	Psychoeducational: problem solving, cognitive restructuring, relaxation
	Cunningham, Edmonds, Hampson, Hanson (1991)	Group psychoeducational program
	Greer, Moorey, Baruch, et al. (1992)	Individual psychoeducational
Educational	Dodd (1983)	Information related to disease and treatment
	Hagopian (1991)	Newsletter
	Hagopian & Rubenstein (1990)	Information by phone
	Lemaire & Lenz (1995)	Information program
	Lorig & Holman (1993)	Self-management program
Individual Supportive	Gordon, Friedenbergs, Diller, et al. (1980)	Psychosocial intervention
	McCorkle, Benoliel, Donalson, Georgiadou, et al. (1989)	Visits at home
Group Supportive	Roberts, Baile, Eldins & Cox, 1990	Group Support
	Spiegel, Bloom & Yalom, 1981	Group Support
	Bloom , Ross & Burnell (1978)	Group Support
	Strauss et al., 1986	Group Support
Counseling	Galonka (1977)	Group counseling
	Goldberg & Wool (1985)	Individual counseling
	Linn, Linn & Harris (1982)	Individual counseling
	Maguire, Tait, Brooke, et al. (1981)	Individual counseling
	Cain, Kohorn, Quinlan, Latimer & Schwartz (1986)	Individual versus group counseling
	Spiegel & Bloom (1983)	Group counseling
Peer-Counseling	Farash (1979)	Peer counseling
	Jacobs, Ross, Walker & Stockdale (1983)	Education and peer support groups
	Houts, Whitney, Mortel & Bartholomew (1986)	Counseling by peers via phone and Information
Psychosocial	Vachon, Lyall, Rogers, Cochrane & Freeman (1981)	Group support after mastectomy
	Worden & Weisman (1984)	Psychosocial
Consultation	Weintraub & Hagopian (1990)	Nursing consultation on side effects from treatment
Combination	Capone, Good, Westic & Jacobsen (1980)	1) Face-to face individual structured counseling and 2) Information
	Fawzy, Cousins, Fawzy, Kemeny, Elashoff & Morton (1990)	1) Group psychoeducational: relaxation and problem solving 2) Group support
	Ferlic, Goldman & Kennedy (1979)	1) Crisis intervention, Information, and2) Group Support
	Cunningham & Tocco (1989)	1) Group psychoeducational and 2) Group Support
	Telch & Telch (1986)	1) Group psychoeducational and 2) Group support
	Grassman (1993)	1) Educational and 2) Support programs

Though an increasing number of clinical trials are taking place, the studies to-date are far from comprehensive in 1) identifying which treatment components were most effective (most studies report only on the effectiveness of the whole treatment versus no treatment); 2) determining at what specific strength the treatment was effective; and 3) describing for whom the treatment was most effective. To insure intervention program effectiveness, there is need for tests of alternative interventions or different components within the same trial, instead of additional clinical trials (Meyer & Mark, 1995; West, Aiken & Bryant, 1996), as well as a need to examine which specific treatment component is best for which specific patient category.

Most intervention studies are "black box" (Ashby, 1956) models. Inputs/treatments are manipulated or observed, and there is then an attempt to relate the variations of output to input, without considering other covariations (Lipsey & others, 1985; Kleiman, 1986). In order to understand the transformational relationships between treatment and outcome, one must also examine the contextual and mediating factors under which the conversion process occurs (Chen & Rossi, 1983; 1987; Cordray, 1989; Costner, 1989; Lipsey, 1993). This process is specified as treatment theory or "causal theory" by Chen (1992).

Braden and colleagues (1990) designed an intervention methodology to test five alternative oncology supportive care interventions. Each intervention relied upon middle range substantive nursing theory. The data from the SHIP program, coupled with the

prominent knowledge related to treatment theory, provide now an opportunity to identify which SHIP treatment interventions and which specific activities/ingredients among the SHIP treatments work best in supportive care of patients. With those findings, clinical relevancy of the Ship interventions can be advanced. The data also make possible the identification of group demographics, diagnoses and treatment characteristics of the afflicted women in the study, as well as how those areas of interest interact with specified interventions. The goal of this study is to determine from those data the means by which those women can be better matched to interventions which should work best for them as individuals. This secondary analysis study of data from the SHIP research has explicitly specified and tested a treatment theory in order to: determine benefits among the components of SHIP interventions, and profile the characteristics of the women most benefited. This study tested the processes by which SHIP interventions affected outcomes in selected positive, 'well-being' issues of breast cancer patients.

Definition of Terms

Terms are used with various meanings within as well as outside a specific discipline such as Clinical Nursing Research. Often, terms are used without being clearly defined; rather meaning may be only implied. In this section, terms are defined as related to the context of this particular study. Table 1.2 provides definitions that were chosen from a broad range of sources involved in the field of interventions research and evaluation research. Sources for the selected definitions included : nursing, health

Table 1.2 Denifitions of terms Being Used in this Study

TERMS	DEFINITIONS	REFERENCES
Therapy	refers to any medical therapies rendered to women with breast cancer by healthcare providers. Relevant therapies in this study's sample include surgery, radiation therapy, hyperthermia, and pharmacological therapy (chemo and hormone)	Holleb, Fink & Murphy (1991)
Treatment or **Intervention**	refers to any planned effort designed to produce changes in the target population, in this case women with breast cancer. Treatment and **intervention** are referred to interchangeably.	Rossi & Freeman (1993)
Outcome	refers to results of an intervention	Lang & Marek (1992)
Impact	refers to the extent to which an intervention causes changes at a higher level than the population under study i.e. society	Rossi & Freeman, (1993) Sechrest (1996)
Efficacy	refers to the extent which an intervention can produce the desired change in the outcome.	Green, Kreuter, deeds & Partridge (1980)
Effectiveness	is the extent to which the achieved efficacy is beneficial to actual practice.	Green, Kreuter, Deeds & Partridge (1980)

education, psychology, research methodology, and health services. The definitions reflect an *evaluation research* perspective.

Statement of the Problem

The problems addressed in this study were: 1) the need for studies that test relative efficacy of components in an intervention so as to aid in future intervention improvements, 2) the need for studies to address specifics of which intervention works best for whom; and 3) the need for examination of contextual and mediating factors in order to better understand transformational relationships between treatment and outcomes. All of the above are necessary to facilitate integration of effective SHIP interventions into effective clinical practice.

Statement of Purpose

The primary purpose of this study is to further develop treatment theory for SHIP interventions. The first objective of this study was to determine which of the five interventions resulted in significant improvement of patients' perceptions of 'well-being'. The second objective of this study was to assess the stability of SHIP interventions' effects during the follow-up period. That is, this study attempted to 1) determine which SHIP interventions and which activities in those identified interventions were most beneficial in promoting perceived 'well-being' in women receiving adjuvant therapy for breast cancer; 2) profile which individuals were most likely to benefit from specific SHIP

interventions, and 3) test the processes by which the SHIP interventions affected the outcomes.

Background of the Problem

Breast Cancer: Incidence, Risk Factors, Diagnosis, and Treatment

Breast cancer remains a significant public health problem in the United States. Breast cancer is probably the most feared cancer in women because of its frequency of occurrence and its psychological impact on those women. In 1992, 43,068 deaths from breast cancer were reported (American Cancer Society, 1996). The American Cancer Society (ACS) estimated that in 1996, breast cancer would account for 31% of all cancer in U.S. women, and that a total of 184,300 new cases would be diagnosed in that year (Parker, Tong, Bolden & Wingo, 1996). The ACS estimated that a woman's risk of developing breast cancer sometime in her lifetime has increased over the past four years from one out of nine (11%) to one out of eight (12.5%) (ACS, 1996).

Plotkin (1996) argued that the increased incidence of breast cancer is due to : 1) women living longer; 2) more women being in the breast cancer prone age group, and 3) increasing use of mammography. After adjustments for today's longer life-span and population bulge of Baby Boomers, the proportion of women who died from breast cancer has remained the same since the 1930s (Plotkin, 1996). Thus, based on current estimated incidence rates and death rates, there will be more women who develop breast cancer than ever before.

The five-year survival rate of women with breast cancer has been climbing. The five-year survival rate for breast cancer between 1960 and 1963 was 62%, and 84% between 1986 and 1991 (ACS, 1996). This improving trend is expected to continue (Mayer, 1988; Parker et al., 1996). Meeting the needs of survivors, as well as helping them adjust to their illness, is a major concern (Fredette, 1995; Holland, 1988; Mullan, 1988; and National Cancer Institute, 1988).

The source of breast cancer is still unknown; however, some associated factors are more widely accepted than others. Specified categories of women are more at risk than others. The "typical" profile of breast cancer patients is: middle age, family history of breast cancer, early menarche, late menopause, and nulliparity (Bilimoria & Morrow, 1995). Although the incidence of breast cancer increases with age (Plotkin, 1996), breast cancer also has been detected in younger women. Younger women's risk of developing breast cancer is one in 26 (40-59 years of age), and one in 14 (60-79 years of age), versus one in eight for women of all ages (Parker et al., 1996).

The detection of breast cancer uses three main modalities: breast self-examination (BSE), clinical physical exam, and imaging technique such as mammography. About 90% of all palpable breast cancers are detected by the patients themselves (Scanlon, 1991). Breast cancer is typically preliminarily confirmed by tissue biopsy. The definitive diagnosis of breast cancer and its staging are made by histological examination of tissue obtained from biopsy.

According to the histological findings, identification of patients' breast cancer can be narrowed down to a specific type from a pool of possible types. A few prominent types are: NOS (cancer, not otherwise specified), intraductal, invasive ductal, inflammatory, papillary, tubular, lobular, invasive lobular, and Paget's (Scanlon, 1991).

Staging of breast cancer, together with patients' characteristics, usually serves as a guide for primary and adjuvant therapy choices. The most accepted primary therapy for breast cancer is surgery including: lumpectomy, partial mastectomy, quadrantectomy, subcutaneous mastectomy, total mastectomy, modified mastectomy, and modified-radical mastectomy. Surgical modalities are procedures for which an attempt is made to remove as much affected tissue as possible. Adjuvant therapies aim mainly to destroy any suspected residual cancer tissue. Mainstream adjuvant therapies include chemotherapy, hormone therapy, radiation therapy, and hyperthermia therapy.

Breast Cancer and Its Impact

Individuals diagnosed with breast cancer face not only physical distress, psychological distress, and uncertainties (Cella, Orofiamma, Holland, Silberfarb, et al., 1987; Cunningham, Edmonds, Hampson & Hanson, 1991; Hobfall & Walfisch, 1984; Weisman & Worden, 1976-1977; Worden & Weisman, 1975), but also social disruption (Freidenberg, Gordon, Hibbard et al. 1981-1982; Greer & Silberfarb, 1982; Meyerowitz, 1980) The uncertainties include possibility of disfigurement, anxiety over body image, disability, discomfort from the disease, discomfort of treatments, discomfort from side-

effects, uncertainty of treatment outcome, uncertainty of recurrence, and uncertainty as to possible death (Kriss, 1981; Plotkin, 1996). The experience of breast cancer is exemplified by Eileen's experience described earlier.

Responses to these uncertainties are influenced by many factors including: knowledge regarding treatment choices, expected side effects, knowledge of available resources, and learned coping skills. Interventions aimed at assisting patients in dealing with their illness are becoming a more consistent part of oncology support programs. There is some evidence that suggests lessening patients' dysfunction through supportive care services benefits patients' length of survival (Spiegel, Kraemer, Bloom & Gottheil,1989).

Supportive Care Services

Supportive care services have gained increasingly more recognition as part of the comprehensive treatment package for patients with cancer (Belani, Belcher, Sridhara & Schimpff, 1994; Byrne & Carney, 1993; Forbes, 1994). A journal, Supportive Care in Cancer, wholly dedicated to supportive care, was created in 1993. Recently, supportive care has been adopted by the National Coalition for Cancer Survivorship (NCCS) as an imperative for quality cancer care (Clark, Stovall, Leigh, Siu, Austin and Rowland, 1995). Specifically, NCCS proclaims that people with cancer should have access to a full range of supportive care services, including psychosocial services and self-help training. The emphasis on supportive care services is quality of survival, rather than survival

alone. Supportive care services aim to assist patients in coping with their illness. Included in supportive care services are: 1) child care; 2) home care; 3) hospice care; 4) pastoral care; 5) transportation; 6) functional care (MacVicar, Winningham & Nickel, 1989); 7) counseling (Farash, 1979; Galonka, 1977; Mcquire, Tait, Brooke, Thomas & Sellwood, 1980; Spiegel & Bloom, 1983; Weintraub & Hagopian, 1990); 8) volunteer support (Bloom, Ross & Burnell, 1978; Gilden, Hendryx, Clar, Casia & Singh, 1992); 9) cancer hotline; and 9) psychological support (Spiegel, Bloom & Yalom, 1981). Of all listed services, psychosocial concerns of patients and their families is the category most frequently identified by patients as a need (McKenna, 1991). Similarly, Sullivan, Weinert and Fulton (1993) underscored McKenna in reporting that of all self-identified needs of patients who are living with various types of cancer, the three most frequently mentioned are coping, knowledge, and support.

Psychological and Educational Interventions as Supportive Care

During the past decade, various combinations of supportive care services have been proposed and tested with increasing frequency by various researchers in diversified populations. Within the adult health area, clinical trials are limited in breadth, and are related mostly to either the populations of mental health patients or those with chronic illness.

For those patients experiencing chronic illness, some researchers emphasize more the educational and informational aspects of supportive care rather than the psychological

aspects. For example, Lorig and Holman (1993) proposed and tested a self-management program for individuals with arthritis. The self-management program was effective in enhancing subjects' self-efficacy level, which in turn affected their overall health status. Similarly, Keefe and Van Horn (1993) evaluated a cognitive-behavioral program for managing arthritis pain, and found that the program was effective. Likewise, in a cancer population, Dodd (1983; 1984) proposed and tested effects of an information program on self-care and its affect upon psychological state. Analysis of Dodd's report indicates that the informational program was effective only in improving patients' knowledge of treatment side effects and patients' self-care behaviors. The psychological state of the patients was not improved by Dodd's interventions.

Lack of Strong Clinical Trials

Most clinical trials completed to-date are "black box" type studies wherein inputs/treatments are manipulated or observed, and there is an attempt to relate the variation in the output to the input, without considering other covariations (Fairurn et al., 1995; Gilden et al., 1992; Gillis, Gortner, Hauck, Shinn, Sparacino & Tompkins, 1993; Greer, Moorey, Baruch, Watson, Robertson, Mason, Rowden, Law & Bliss, 1992; Olmsted, Davis, Garner, Eagle, Rockert & Irvine, 1991; Silverman, Musa, Martin, Lave, Adams & Ricci, 1995; Stravynski, Verreault, Gaudette, Langlois, Gagnier & Larose, 1994; Vlaeyen, Haazen, Schuerman, Kole-Snijders & van Eek, 1995). Few studies evaluated the covariations among interventions, outcomes, mediators, and conditioning

variables (Glick, Clarkin, Haas & Spencer, 1993; Marlow, West, Corrigan, Pena & Cunningham, 1994; Zeltzer, Dolgin, LeBaron & LeBaron, 1991). Often the "black box" studies ignore that the problem situations are complex. Most often, intervention studies are modeled with the simple structure of: 'A' lead (not) to 'B'. In reality, the structures are complex and relationships between 'A' and 'B' may be multidimensional. 'A' may affect 'B' through a series of mediators: 'B_1', 'B_2', 'B_3' etc. Moreover, the effect on 'B' by 'A' may be moderated by many other factors. There is a misfit between the research representation versus the substantive reality of interest (Brinberg & McGrath, 1985). In sum, "black box" studies oversimplify reality. That is, "black box" studies underrepresent reality; therefore, obtained results are crude and distorted.

Lack of Specificity in the Components of Interventions, and Lack of Specifics as to What Works Best and for Whom

Many of the reported studies tested only one alternative intervention offered to a homogenous group of patients; therefore, it is difficult to differentiate which intervention was most effective and most appropriate for a particular type of patient (Meyer & Mark, 1995). Additionally, many studies failed to evaluate which components of the treatment were efficacious. Much needs to be known about the relative efficacy of various individual or combined intervention approaches...a tailored approach. Tailored approach interventions reflect realities in day-to-day clinical settings, and thus are more clinically relevant (West, Aiken, & Bryan, 1996).

Although many psychoeducational intervention studies demonstrate efficacy of health-care interventions as they apply to helping clients cope with their move towards regaining and maintaining their normal life, there is limited implementation of these interventions in real life clinical settings as compared to research settings. This lack of implementation may be due to inconsistent findings of treatment efficacy (Watson, 1983) and lack of detailed specificity in the components of the interventions offered to subjects (Liang, Dunn, Gorman & Stuart-Harris, 1990).

SHIP: A Psychoeducational Interventions Program - A Test of Multi-Component Interventions

Braden and colleagues (1990) used the "Self-Help Model" (Braden, 1990b) as substantive theory in forming the design of the Self-Help Interventions Program (SHIP). SHIP was designed to aid women who were experiencing primary therapy for breast cancer. The SHIP consisted of three components: cognitive/educational, psychological, and combination of both. SHIP interventions were tested and demonstrated to be effective in maintaining or increasing quality of life outcomes (Kreulen, 1994; Sidani, 1994). That is, SHIP interventions, as an inputs, affect outputs or outcomes such as life quality/well-being, as perceived by participants in the SHIP. However, the specifics of how SHIP worked to affect 'well-being' needs further examination.

A secondary analysis of data from the SHIP study was under taken in order to determine: 1) which components of the SHIP interventions were most effective? 2) what

were the active ingredients within each SHIP's component? 3) for whom were the SHIP interventions most effective? 4) what were the steps that the SHIP interventions brought about in order to change the output? 5) which other variables functioned as mediators in the change process? 6) which conditioning variables influenced the interventions' effects on the outputs? and 7) if the treatment was effective, how sustained was the effect? These questions are integral to "treatment theory" (Lipsey, 1993). Addressing these concerns will: 1) provide a fuller picture of the woman's first year of breast cancer experience; 2) optimize the SHIP interventions' effects; 3) help tailor an intervention's components to meet patients' needs; 4) improve the probability for program implementation; as well as 5) contribute to the general knowledge on psychoeducational treatment theory.

Significance of the Study

The Issue of the "Black Box"

Most causal phenomena of practical interest are complex. One such phenomenon is how women experience and deal with breast cancer (Anonymous, 1994; Ganz, Lee, Sim, Polinsky & Schag, 1992; Geyer, 1993). This process involves multidimensional interactions that are extended over time in a complex multi-step causal process wherein variables such as personal and medical characteristics accompany and interact with outcomes (Lipsey, 1993). In order to understand the transformational relationships between treatment and outcome, one must additionally examine the contextual factors, as

well as the mediating factors, under which the conversion process occurs (Chen & Rossi, 1983; 1987; Cordray, 1989; Costner, 1989; and Lipsey, 1993).

The Issues of Component Specificity and Individuals' Variability

Only when the empirical facts of the active ingredients, beneficiaries, and the process are known, can SHIP interventions be translated into everyday clinical practice with interventions consistently demonstrating expected results. Knowing which ingredients in the SHIP interventions are active will contribute toward optimizing the efficiency of the appropriate intervention in terms of time, effort, and dollars versus outcome effects. Knowing which ingredients are necessary for bringing about a desired change in an outcome can trim time and effort required of a patient with regard to a specific intervention so that it can be more attractive to the patient beneficiaries. For instance, a woman may be more willing to experience an intervention that is 45 versus 90 minutes long, or four versus six sessions. Likewise, a health-care financier may be more willing to endorse and pay for an intervention that costs less, yet is equally effective.

Another important aspect of analysis is the variability within each treatment component. Individuals may react differently to the same treatment condition, depending upon contextual factors. Knowing the profile of the women who gain the most from the specific SHIP intervention will initially help in determining the beneficiary group for which the intervention can most appropriately be implemented. The emphasis of this study is on individual patient outcome differences over time. Thus, the error of

inappropriately generalizing treatments to those for whom the treatments are ineffective can be avoided.

The Issue of Strong Clinical Trial: Treatment Theory and Clinical Relevancy

"Black box" research fails to examine the causal process, components' specificity, and individual variability. Treatment theory is an alternative research paradigm to "black box" research. Treatment theory emphasizes understanding how a treatment works, which intervening variables are critical, which interactions with subjects and settings occur, and how the extra-treatment factors influence positive change in individuals (Chen & Rossi, 1983; 1987; Cordray, 1989; Costner, 1989; and Lipsey, 1993).

Given that the SHIP program is effective, and that the SHIP interventions improve life quality and perceived well-being, the cause and effect statement can be strengthened substantively by use of explicit treatment theory to specify the nature and details of the change mechanism. Only when SHIP interventions are clearly delineated are they more likely to be implemented in clinical areas, and have a greater probability of achieving desired outcomes. Moreover, understanding how treatments affect outcomes provides information useful for estimating the validity and value of an intervention. The value of a treatment is key in the decision making process by policy makers and financiers as to whether or not a treatment is implemented.

This study, guided by treatment theory, aims to address: 1) the causal process in the SHIP interventions; 2) the treatment strength, components, and ingredients; and 3) the

specific beneficiaries of SHIP interventions. All are necessary to facilitate integration of effective SHIP components into clinical practice.

Summary

The problem of breast cancer in women is immense with regard to numbers of persons experiencing this illness. Like other chronic illnesses, breast cancer is a stressful event in the life of newly diagnosed patients and those patients currently undergoing cancer treatment. Psychoeducational interventions designed to enhance the patients' ability to deal with emotional and physical problems associated with breast cancer are necessary. The SHIP's psychoeducational interventions can be used to assist those patients in coping with and recovering from breast cancer.

SHIP interventions have been tested. However, the strength of the interventions and the interactive profile of the beneficiaries of the SHIP interventions, that is the "treatment theory" aspect of the SHIP interventions, needs further evaluation. There is a need to address various critical aspects related to the value of SHIP interventions, active ingredients within each SHIP component, specific beneficiaries of SHIP interventions, and process steps by which the SHIP interventions bring about changes in patient outcome variables. In this study, these issues will be systematically explored by using a theoretical framework which is addressed in the next chapter.

The findings addressing these critical evaluative aspects will not only strengthen the validity of the SHIP interventions, but will also enhance the implementability of the

SHIP interventions to real life clinical settings. Ultimately, the findings should aid in optimizing psychoeducational treatments in clinical settings.

CHAPTER II

THEORETICAL FRAMEWORK

In this chapter, the theoretical model underlying the study is described in detail. Discussion of the treatment framework includes its derivation, underlying assumptions, major propositions, specific variables, and definitions. Review of the literature includes 1) the cancer experience; 2) hypothesized relationships concerning conditioning variables; and 3) the effects of various types of supportive care interventions related to proximal outcomes and distal outcome variables in patients.

Overview of the Framework

Derivation of Treatment Framework

A psychoeducational program is an organized effort to intervene in an ongoing process such as assisting individuals live with their illness. How to structure these organized efforts appropriately so that they will lead to desirable outcomes is delineated by the treatment framework put forth in this study. The explicit treatment framework of this study aims to explain individuals' change's in outcomes resulting from SHIP interventions, and is an integration of substantive theory with treatment theory.

Substantive Theory

Substantive theory is also referred to as "normative theory" by Chen (1989). Substantive theory is the theoretical structure of a study, i.e. an intervention; it provides theoretical guidance in the design of the intervention, i.e. education versus counseling.

Besides what the treatment should be, substantive theory prescribes precisely what the treatment goals are. The substantive theory portion of this study is guided by the Self-Help Model (Braden, 1990b).

Self-Help Model. The Self-Help Model (Braden, 1990a; 1990b) (Figure 2.1) emerged from complimentary middle range learning theories of Learned Helplessness, Instrumental Passivity, and Learned Resourcefulness. Learned Helplessness is characterized by an uninformed response process, a withdrawal from manageable adversities, and thus a succumbing to everyday problems (Seligman, 1975).

Uninformed processes can result from an inability to determine meaning of events or cognitive/motivational/emotional deficits that follow exposure to events. Similar to learned helplessness is Instrumental Passivity in which patients' past independent and active behaviors are discouraged (Baltes, 1982; Baltes, Burgess & Stewart, 1980; Baltes & Skinner, 1983).

The extent of cognitive, motivational, and emotional deficits exhibited by patients is dependent on the dependency-promoting reinforcers present in their environment. Learned Resourcefulness, the opposite response, represents an informed process of facing adversities by employing skills (enabling skills) learned from trial and error (Haug & Lavin, 1983) or past experience (Rosenbaum, 1983).

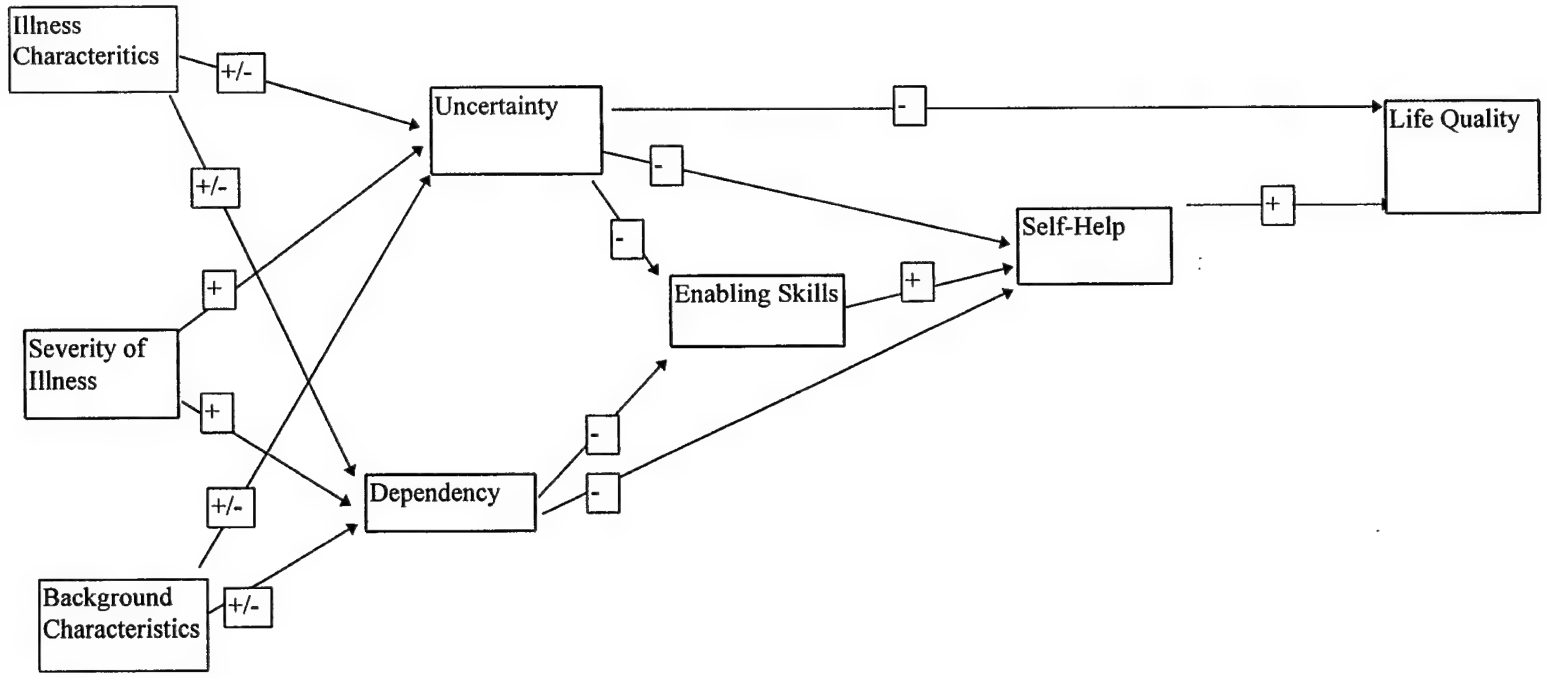
The Self-Help model describes the process of how self-help and life quality can be affected in response to chronic illness. Uncertainty associated with one's illness plus

one's own abilities determines a person's engagement in the learning process used to deal with the situation. Eileen, who was depicted in Chapter I, determined that she needed to know more about breast cancer in order to deal with the ever present uncertainties. The effects of the cancer stressor on adjustment are moderated by resources available to individuals, and are mediated by individuals' perceived level of uncertainty inherent to the situation (Figure 2.1).

Enabling skills are learned and accumulate over time. The Self-Help Model recognizes the resiliency in people based upon their own skills and resources which mediate the effects of adversities on their well-being. Self-Help model substantive theory holds that if a person's repertoire of skills (enabling skills) is enhanced, and if the person feels less uncertain about the illness experience, then with a decrease in uncertainty and an increase in goal attaining behaviors of self-help and self-care, psychological adjustment and the person's overall well-being are maintained or enhanced.

Interventions based on the Self-Help Model aim to decrease patients' dependency and uncertainty, improve patients' resources or skills, and facilitate patients' self-management. Based on findings supporting the mediating role of enabling skills (Braden, 1991; 1992; 1993; Braden, McGlone & Pennington, 1993; Regan, Lorig & Thoreson, 1988), the Self-Help Interventions Program (SHIP) was formulated with two main components. The first component, educational and behavioral interventions, aimed to 1) enhance clients' knowledge of breast cancer, its treatment, the treatment side effects,

Figure 2.1. Self-Help Model (Braden, 1990)



and available resources to the patient; and 2) improve clients' coping or enabling skills of problem solving , cognitive reframing, and belief-in-self. The second component, psychological interventions, aimed to assist clients in dealing with uncertainty and/or reframing uncertainty in a different and positive perspective, one of challenge rather than threat. Thus, the present study tested part of the Self-Help Model (Figure 2.1). Specifically, the present study tested: 1) conditioning variables such as Illness Characteristics' effects on Level of Uncertainty while undergoing SHIP interventions; 2) the effects of SHIP interventions on Enabling Skills; 3) the effects of SHIP interventions on Self-Help; 4) the effects of SHIP interventions on Life Quality; 5) the effects of SHIP interventions on Life Quality through Enabling Skills, and 6) the effects of SHIP interventions on Life Quality through Self-Help.

Treatment Theory

Complimentary to the substantive theory, treatment theory or "causal theory" (Chen, 1989) specifies how the designed program works and under what conditions. Treatment theory provides the link between concepts or steps using variables of substantive theory to explicate treatment process patterns. Treatment theory addresses issues such as what intervening and conditioning variables could mediate the relationships between the treatment and outcome. The mechanism of how SHIP interventions work is grounded partly in the substantive theory. For instance, how a woman copes with her breast cancer depends on resources, i.e. information, support

available to her. The primary basis for how interventions work is by strengthening resourcefulness, or specifically the enabling skills of problem solving, cognitive reframing, and belief-in-self.

Treatment theory underscores the need for a theory based upon intervention research. Treatment theory holds that all aspects of intervention research must be linked to theory (Chen, 1992). A theory oriented study is considered to be a necessary precursor to valid design, strong methodology, and stronger causal inference of treatment effectiveness (Costner, 1989; Finney & Moos, 1989). Theory-oriented evaluation emphasizes an understanding of the transformational relationship between treatment and outcome, in addition to the contextual factors under which the conversion process occurs, and is an alternative to "black box" research.

Treatment Framework of SHIP Interventions

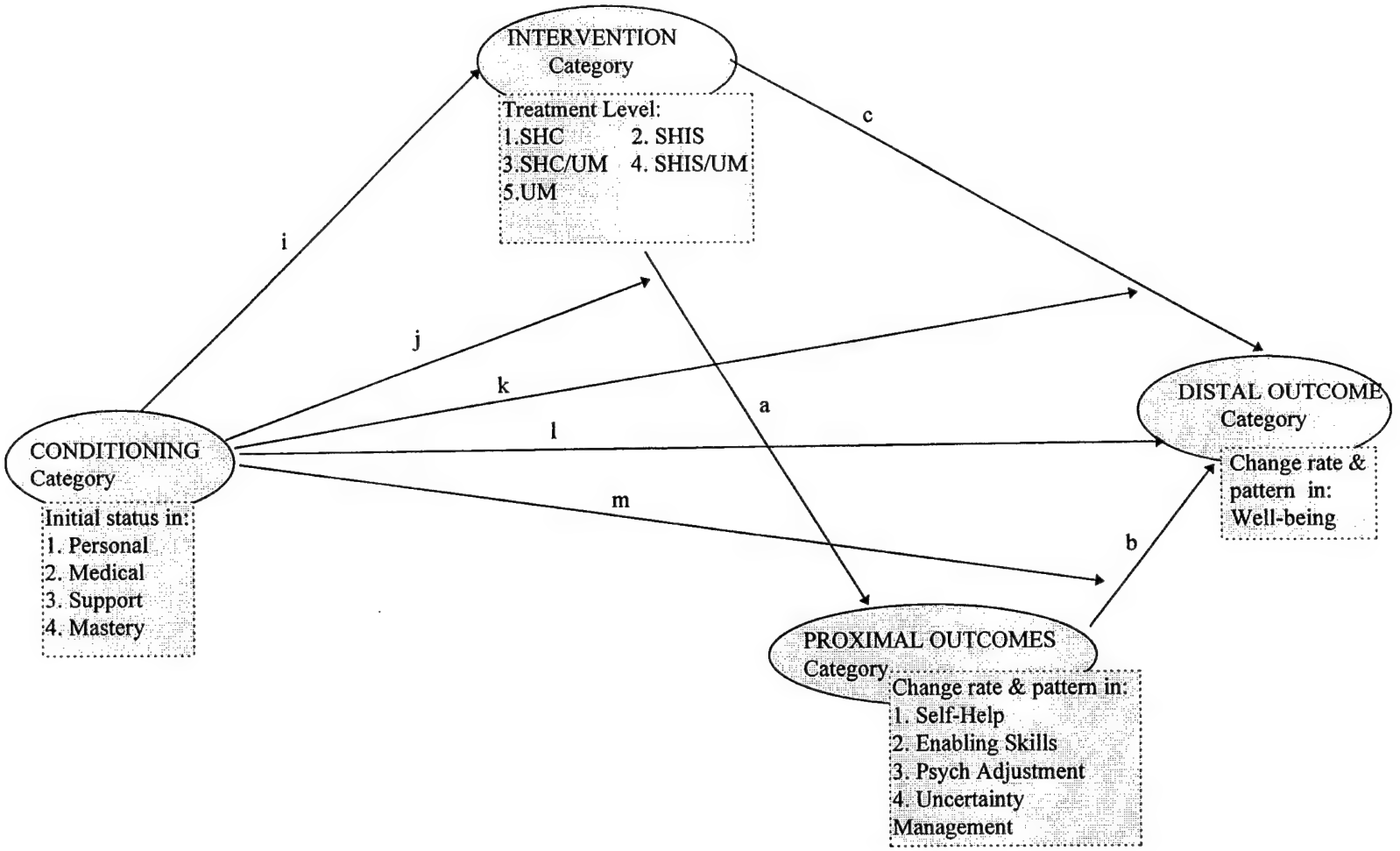
Due to the complex nature of stress and coping, combined with the scarcity of knowledge related to the effectiveness of health-care interventions, it is necessary to integrate multiple theories in order to fully explain the process of coping with breast cancer. Substantive theory guides the design of the interventions, and the treatment theory guides the process of estimating the effective level of the specific intervention. Therefore, a treatment framework (Figure 2.2) derived from substantive and treatment theories provides an organizational framework for evaluating SHIP interventions. Categories of concern within the treatment framework are organized in explaining how

SHIP interventions would work. Categories (conditioning, intervention, proximal outcomes, and distal outcome) are discussed in detail in the following section.

Conditioning Category. The first category in the treatment framework is Conditioning. Conditioning refers to personal characteristics of the patient and her medical status. Conditioning also concerns 1) the physical, emotional, and financial support available to the clients; and 2) the level of self-confidence or self-sufficiency also known as mastery in the clients (Figure 2.2).

The women's "initial status", "intercept", and "rate of change" were of interest in this study. Initial status and intercept are related to the Conditioning Category. Rate of change is related to outcomes, and will be discussed in detail under Proximal Outcomes and Distal Outcome Categories. Initial status or initial level refers to the individual's actual score on variable X at entry into a treatment. Initial status is depicted as score $\mathbf{x_0}$ in Figure 2.3. Intercept is the individual's average score on variable X over time. Intercept is depicted as $\mathbf{a_1}$ in Figure 2.3; "$\mathbf{a_1}$" is the average of $\mathbf{x_0}$ and $\mathbf{x_1}$. Initial status addresses the issue of whether or not individuals' variations of change are systematically due to some known individual characteristics. For example, women's rate of change in adjustment is related to patients' perceived support level prior to entry into a SHIP intervention. That is, women with higher perceived support adjust differently than women with lower perceived support. Thus, the individual's change depends upon the

Figure 2.2. Treatment Framework, Categories (Conditioning, Intervention, Proximal Outcome, and Distal Outcome), and Variables of each Category for Estimating Effective Level of SHIP Intervention.



individual's initial status $\mathbf{x}_0$. Terms "initial status" or "initial level" are used interchangeably.

Intervention Category. The second category in the treatment framework is Interventions which refers to the SHIP psychoeducational components and treatment strength provided to the women, as compared to conventional care. Psychoeducational components included Self-Help Class (SHC), Self-Help Independent Study (SHIS), Uncertainty Management (UM), and combination of SHC/UM and SHIS/UM (Figure 2.2).

The treatment framework guides the process of estimating the effective level of the specified intervention. Effectiveness of SHIP interventions can be evaluated relative to various aspects: treatment, implementation, outcome, impact, mechanism, and generalization (Chen, 1989). Chen suggests that these aspects can be evaluated individually or in combination. In this study, the effectiveness level of SHIP interventions was evaluated relative to the strength of the specified SHIP intervention. Conceptually, treatment strength included components and strengths of each component.

If the ultimate goal is to have an effective and efficient treatment, then treatment strength should be central in assessing any program/intervention. If delivered as intended and designed, each SHIP intervention should affect a change in Proximal Outcomes and Distal Outcome. Additionally, it is necessary to distinguish clearly among the various components of the total treatment (Sechrest & Yeaton, 1981).

In the present study, the efficacy of each SHIP intervention was evaluated not as a whole, but relative to the strength of each delivered component: SHC, SHIS, UM, SHC/UM, and SHIS/UM. Sechrest and Yeaton (1981) proposed dimensions such as frequency, purity, duration, specificity, intensity, and potency to be considered when evaluating the strength of an intervention. For example, treatment that delivers six weekly (frequency) sessions according to protocol (purity) over a six week (duration) period is stronger than the same treatment that was delivered over a 12 week period.

Strong treatment contains a large amount in pure form of those active ingredients (specificity) i.e. cognitive versus behavioral leading to change. Intensity refers to the proportion of treatment that patients actually received. Patients who attended all six sessions have higher treatment strength (intensity) than patients who attended only three sessions. The strength of a treatment is enhanced if there is a clear and detailed protocol specifying (specificity) the conditions under which it was intended to be delivered. The strength of a treatment is more potent if, for example, the teacher of the Self-Help Class has a masters degree versus bachelors degree, and is trained for the job versus not trained (potency).

Proximal Outcomes Category. The third category in the treatment framework is Proximal Outcomes which refers to patients' change in: self-help, enabling skills, uncertainty management, and psychological adjustment, as a direct consequence of services provided. The treatment framework of this study poses that SHIP interventions

affect the distal outcome not only directly, but also through proximal outcomes (Figure 2.2). This mechanism of treatment effects deals with how and why SHIP interventions generated the observed outcomes. If only the input and output are presented, i.e. intervention and distal outcome, further improvement of a program is not possible, and understanding the mechanism process is not possible.

Without understanding the process, efforts to change or improve the program may in fact have adverse results (Scott & Sechrest, 1989). It is not sufficient to lump together everything that occurs between random assignment and measurement of outcomes. This mechanism process addresses the issue of "black box" research, and examines the processes by which SHIP interventions affect 'well-being' as perceived by women with breast cancer. Understanding how an intervention works, rather than whether or not it works, will strengthen future clinical trials testing program effectiveness.

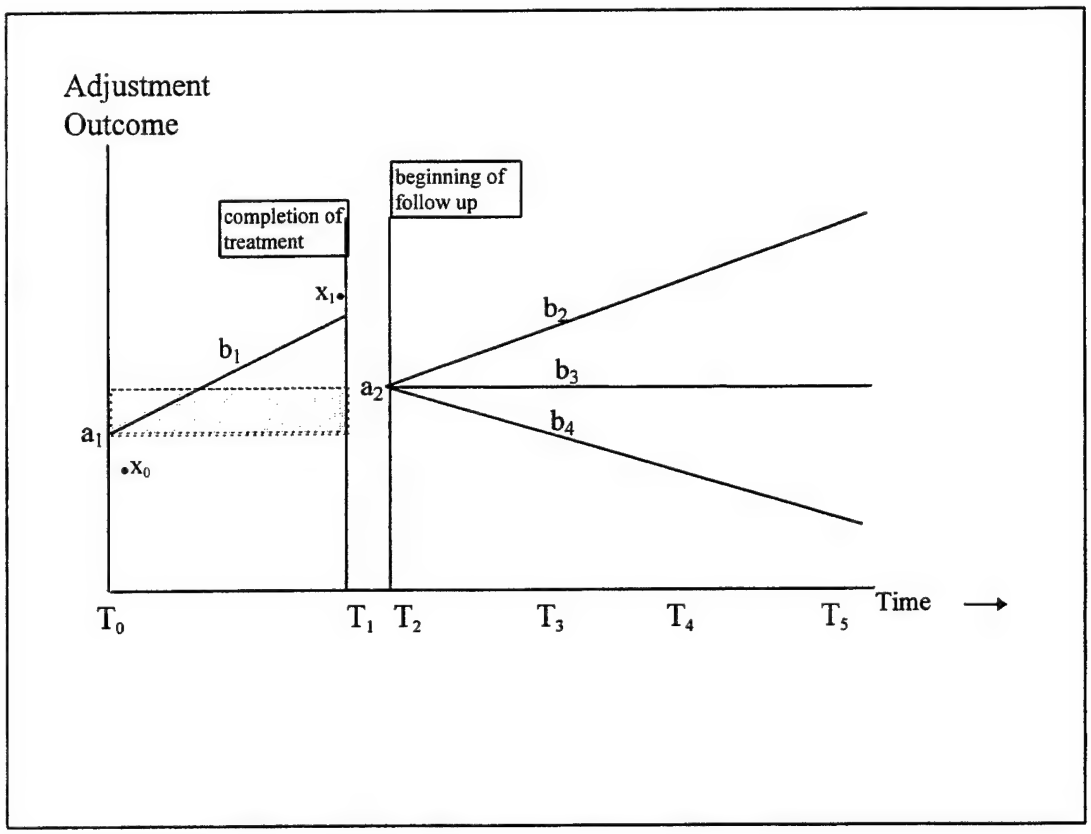
Besides mechanism of effects, of interest to this study was change, also known as "slope". Change varies in pattern and rate (Burchimal & Appelbaum, 1991; Francis, Fletcher, Stuebing, Davidson & Thompson, 1991). The first type of change is change pattern which is change in performance pattern over time. Of interest here are the pattern/shape of the performance slope and pattern/shape variations among individuals in each treatment group: 1) do women adjust quickly (curvilinear) soon after a SHIP intervention, or do they adjust at a more constant rate (linear)? and 2) is the adjustment accelerated quickly for some women, and held constant for others? For example,

stressful events affect psychological distress curvilinearly (Ruch, Chandler & Harter, 1980).

The reasoning behind the curvilinear effect is that persons who have experienced no recent stressful events may not have developed coping strategies and, in face of crisis, have little experience in dealing with the situation. Likewise, those who have experienced many stressful events may also be influenced adversely by the "stress effect". On the other hand, for example, pro-deviant attitudes during adolescence change constantly or linearly during ages 11 to 18 (Raudenbush, 1995). Together, intercept and slope can help in explaining the linearity versus curvilinearity change patterns.

"Intercept" score on adjustment during the treatment period can be compared to the "intercept" score of the follow-up period to reflect or capture treatment effect (McArdle & Hamagami, 1991). "Intercept" score of treatment period is depicted as $\mathbf{a}_1$ in Figure 2.3, and "intercept" score of the follow-up period is depicted as $\mathbf{a}_2$ in Figure 2.3. For example, a woman has a treatment intercept score of 50 on adjustment, and a follow-up intercept score of 75, which means she improved 25 points on adjustment, with the gain being a result of the treatment. The shaded area in Figure 2.3 reflects this gain. However, in the present study all six data points (baseline, post-intervention, and follow-ups) were calculated and analyzed as overall change in performance over time. Essentially, slopes represent sustained treatment effect over the one year follow-up period.

Figure 2.3 Illustration of Treatment Effect and Change Processes.



Notes:

$\mathbf{x_0}$ = "initial status" or "initial level", refers to the individual's actual score on variable X at entry into a treatment.

$\mathbf{a_1}$ and $\mathbf{a_2}$ are "intercept". Intercepts are individuals' average score on a variable over time. For example, "$\mathbf{a_1}$" is the average of $\mathbf{x_0}$ and $\mathbf{x_1}$.

$\mathbf{a_2}$ - $\mathbf{a_1}$ = treatment effect (shaded range).

$\mathbf{b_1}$ indicates rate of change during treatment period, whereas $\mathbf{b_2}$, $\mathbf{b_3}$, $\mathbf{b_4}$ are possible changes in performance during follow-up.

The second type of change is rate of change in performance over time. Of interest here is the change value or parameter. Are the change values constant across subjects, or does the magnitude of certain values vary? For example, although all women show constant response to a specific SHIP intervention, is it more constant for some women than for others? In addition, the positive or negative sign of the change value gives the direction of change over time (McArdle & Hamagami, 1991). In Figure 2.3, a level of change in $\mathbf{b}_1$ indicates treatment effect; a change in $\mathbf{b}_2$, or $\mathbf{b}_3$, or $\mathbf{b}_4$ indicates long-term treatment effect.

The emphasis here is on individual change and the correlates of change: pattern and rate which can be accomplished through individual growth curve analysis. The focus on the correlates of change comes from the fact that individual change is better illustrated by both change pattern and change rate. For example, women are responding at a constant rate to a SHIP intervention, but patient A responds positively while patient B responds negatively.

Distal Outcome Category. The fourth and last category in the treatment framework is Distal Outcome. Similar to the Proximal Outcomes Category, Distal Outcome refers to the pattern and rate of change in the clients as an indirect consequence (Mayer, 1996) of a specified SHIP intervention.

The focus of this study was to examine 1) how a specified initial status, such as personal characteristics, affects the subject's participation in a SHIP intervention; 2) the

relationship between the change pattern and rate to a SHIP intervention versus patients' initial status of conditioning factors: educational level and mastery level; 3) the change pattern and rate and change of proximal outcomes to a SHIP intervention; 4) the change rate and change pattern of distal outcome to a SHIP intervention; and 5) whether a change in rate and pattern in proximal outcomes will lead to a similar change in distal outcome.

Theoretical Assumptions

The following are assumptions inherent to the proposed integrated framework.

i. The person is constantly evolving, and is responsible for his/her own health.

ii. Health is a dynamic state manifested by one's perceived well-being.

iii. Experiencing chronic illness introduces one to a learning frame.

iv. Some changes and hardships are facts of life. Thus, changes such as getting a job or relocation of residence are expected and routine. However, change such as experiencing breast cancer is not only unexpected but is also not normal; major change such as illness requires major adjustment.

v. Over time, individuals learn/develop basic skills/strategies designed to foster growth as well as to protect them from routine changes and hardships.

Major Propositions of the Framework, Variables Included, and Definitions of Included Variables

In this section, major propositions are organized in relation to each of the categories: conditioning, intervention, proximal outcomes, and distal outcome. Additionally, variables included in each category, as well as definitions, are presented. Specific hypotheses to be tested, stemming from each proposition, are specified in chapter three.

Based on the framework described earlier (Figure 2.2), several key variables for each category of conditioning, intervention, proximal outcomes, and distal outcome are believed to affect the outcomes of the SHIP interventions offered to women with breast cancer for the purpose of improving their well-being. Both direct and indirect effects between intervention and outcomes are of interest to this present study.

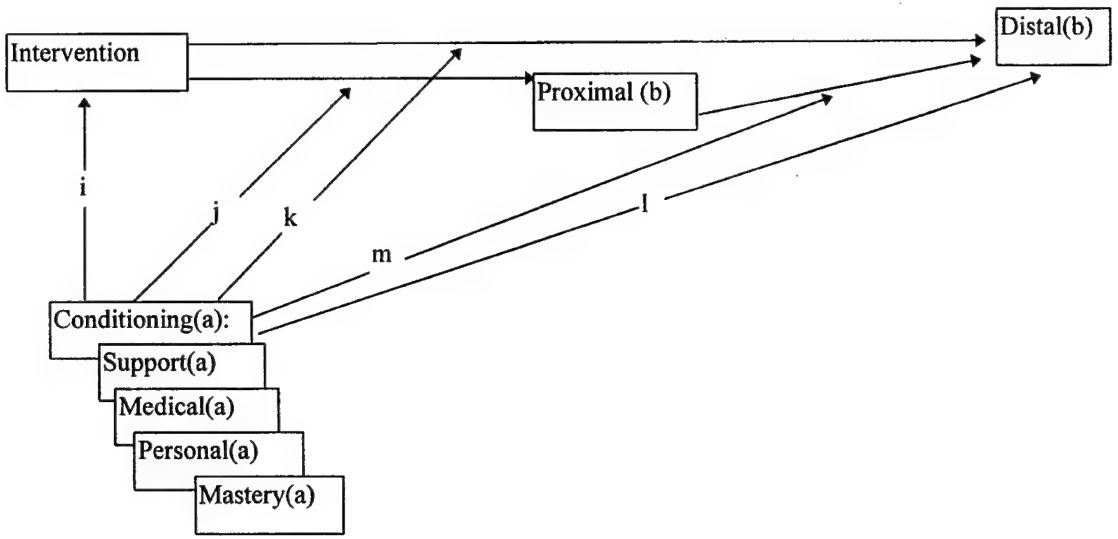
Conditioning Category: Variables, Definitions, and Propositions

Conditioning factors refer to characteristics of the patient, her medical therapy status, and her disease status.

Variables Included in Conditioning Category

The conditioning variables of interest to this present study include personal characteristics, medical characteristics, mastery, and social support (Figure 2.4).

Figure 2.4 Research Variables Included in the Conditioning Category and Its Propositions



Definition of Variables Included in the Conditioning Category

Personal characteristics such as age, education level, and work status are unique attributes associated with each individual. Medical characteristics are an index of the patients' medical status, including "staging" of breast cancer at time of diagnosis, presence of metastasis, type of adjuvant therapy, and presence of other chronic illness. Mastery is defined as the belief in one's self as being capable of influencing one's behavior and overcoming adversities (Pearlin & Schooler, 1978). Social support refers to the need for, size of, use of, and satisfaction with support available to patients (Barrera, 1980), as well as the functioning level between the client and her significant others (Spanier, 1988).

Propositions Related to Conditioning Category

There are five major propositions related to the conditioning category (Figure 2.4).

Proposition #1 - Variables of the Conditioning Category directly affect interventions (**i**). Specifically, variables of personal characteristics and medical characteristics directly affect all variables included in the specified Intervention Category.

Proposition #2 - All variables of the Conditioning Category interact with the intervention relative to proximal outcomes (**j**).

Proposition #3 - All variables of the Conditioning Category influence distal outcome directly (**l**).

Proposition #4 - All variables of medical characteristics, personal characteristics, and mastery of Conditioning Category interact with the intervention and the proximal outcomes relative to the distal outcome (m, k).

Figure 2.4 depicts the interactive effects (j, k, m) upon distal outcome. The effects of the intervention on proximal outcomes or distal outcome differ under various conditions as the conditioning variables take on different values (Costner, 1989; Finney & Moos, 1989).

Intervention Category: Variables, Definitions, and Propositions

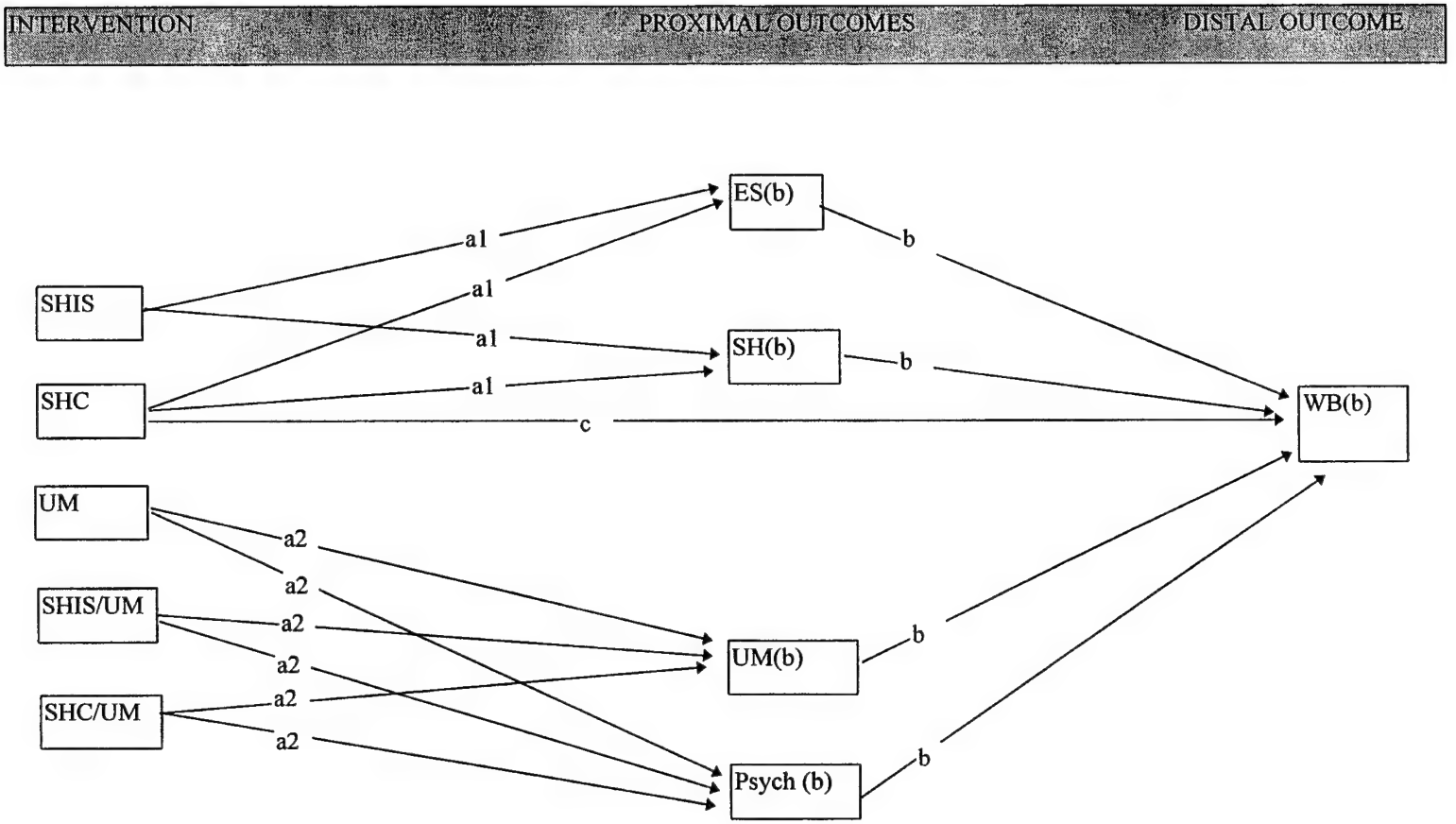
Intervention Category refers to the psychoeducational services provided to the women, as compared to conventional care or natural learning condition.

Variables Included in the Intervention Category

The five components of psychoeducational intervention based on the Self-Help Model (Braden, 1990b) from the SHIP study and the natural learning condition are variables being evaluated in this current study (Figure 2.5). These components/variables are:

1) self-help independent study (SHIS) is a self-study program which was structured to enhance patients' problem solving skills, cognitive reframing skills, belief-in-self skills, and breast cancer information;

Figure 2.5 Research Variables Included in the Intervention Category and Its Propositions



2) self-help class (SHC) contents are the same as self-help independent study, but were delivered to the subjects by trained teachers in a group setting. Group members also interact as participants learn with one another and with the teachers;

3) uncertainty management (UM) is the individualized intervention offered over the telephone by trained nurse-client managers following a standardized protocol to provide counseling and to assist participants in managing their perceived uncertainty;

4) combination of SHIS and UM;

5) combination of SHC and UM; and

6) natural learning condition (NLC). The women assigned to this group were free to learn from where, when, and as much or as little as they chose to. Sources of information could come from magazines, television, or talking to friends or providers. Although these women did not participate in any SHIP components, according to the Self-Help Model, they were normally engaged in trial and error learning on their own. There is potential for some of the women in the natural learning condition group to "learn" as well or as much as women enrolled in one of the SHIP components.

Definition of Intervention Variables Included in the Intervention Category

Components, specific ingredients in components, mode of delivery, and amount of treatment actually received by participants are aspects of treatment strength. Treatment strengths were varied and are of interest in this study. Treatment strength is defined as a specific component's intensity, frequency, and duration of treatment

received by participants (Scott & Sechrest, 1989). Psychoeducational interventions are defined as an organized and interactive learning process using a combination of methods of delivery i.e. teaching, counseling, and behavior modification (Bernier, 1992). The aims of psychoeducational interventions are to enhance patients' knowledge and well-being.

Propositions Related to the Intervention Category

There are three major propositions related to the conditioning category (Figure 2.5).

Proposition #5 - All variables of the Intervention Category directly affect (**c**) distal outcome.

Proposition #6 - Variables SHIS and SHC of the Intervention Category directly affect (a1 in Figure 2.5) variables of self-help and enabling skills of the Proximal Outcomes Category. Whereas, variables of SHIS/UM, SHC/UM, and UM of the Intervention category directly affect (a2 in Figure 2.5) variables of uncertainty management and psychological adjustment of the Proximal Outcomes Category.

Proposition #7 - All variables of the Intervention Category indirectly (**a*b**) affect the well-being variable of the Distal Outcome Category. The Proximal Outcomes Category acts as a mediator between the variables included in the Intervention Category and well-being.

Figure 2.5 depicts the indirect effects (**a1** and **b**, **a2** and **b**) and direct effect (**c**) of variables included in the Intervention Category on well-being of the Distal Outcome Category.

Proximal Outcomes Category: Variables, Definitions, and Propositions

Proximal outcomes are variables thought to be affected immediately after the implementation of interventions (Lipsey, 1990a). Proximal outcomes are related to change in the clients as a direct consequence of the services provided.

Variables Included in Proximal Outcomes Category

Proximal outcomes of interest in this study are: 1) self-help; 2) enabling skills; 3) uncertainty management, and 4) psychological adjustment (Figure 2.5).

Definition of Variables Included in the Proximal Outcomes Category

Self-Help is defined as one's perceived level of performance in adult roles (Braden, 1990b). Enabling skills relates to level of belief-in-self, problem solving ability, and ability to cognitively reframe or view adversity in non negative ways (Rosenbaum, 1983). Uncertainty management is the ability to derive meaning out of events (Mishel, 1988). Psychological adjustment is related to positive and negative mood in reaction to adversities (Watson, Clark & Tellegen, 1988).

Propositions Related to the Proximal Outcomes Category

There is one major proposition related to the Proximal Outcomes Category (Figure 2.5).

Proposition #8 - Proximal outcome variables directly affect (**b**) the distal outcome variable.

Distal Outcome Category: Variables, Definitions, and Propositions

Distal outcome is related to change in the clients as an indirect consequence of the services provided.

Variables Included in the Distal Outcome Category

The distal outcome of interest in this study is operationally defined to be well-being as perceived by women with breast cancer (Figure 2.5).

Definition of Variables Included in the Distal Outcome Category

'Well-being' is defined as the participants' overall sense of satisfaction with life, including physical, psychological, and social functioning (Riecker, Clark & Fogelberg, 1992). Satisfaction with life is a subjective process (Ferrell, 1993; Oleson, 1990). Subjective assessments of life are related to the internal referents of aspiration level and perceived control, in the process of determining overall satisfaction with life (Gutek, Allen, Tyler, Lau & Majchrizak, 1983).

Propositions Related to the Distal Outcome Category

It is proposed that observed change in overall 'well-being', as well as immediate and distant 'well-being' are attributable directly to intervention variables (**c**), proximal outcome variables (**b**), conditioning variables (**l**), and the interaction effects of these variables (**j**, **k**, **m**, **a**).

The "black box" of how input of SHIP's components and treatment strengths affect pattern and change rate of 'well-being' were decomposed further. The treatment strengths in relation to SHIP's components were examined for their contributions to change pattern and change rate in both proximal outcomes and distal outcome. The processes by which the intervention affect change patterns and change rate of the distal outcome (well-being) were investigated.

Review of the Literature

In this section, empirical findings supporting the theoretical propositions are detailed. First, the literature related to the cancer experience is presented to provide the background understanding of breast cancer and its impact. The remaining literature review is organized according to categories and related propositions.

Literature Related to Cancer Experience

When presented with a stressful situation, the person evaluates whether the situation is damaging or potentially damaging, on the basis of her understanding and her available resources (Lazarus & Folkman, 1984). Facing breast cancer is a major stressful situation (Maguire, 1989), and is considered as taxing (Morris, 1979; Frank-Stromborg et al., 1984; Freidenbergs et al., 1981-1982; Lasry et al., 1987). Breast cancer is probably the most feared cancer in women because of its frequency and its psychological impact.

Individuals diagnosed with breast cancer face many uncertainties. Possibility of disfigurement, disability, discomfort of the disease, discomfort of treatments, discomfort

from side effects, or death are major physical concerns. Uncertainty related to outcome from medical therapies, recurrence, role change, and self-image is a major psychological problem (Hilton, 1988; Kriss, 1981; Loveys & Klaich, 1991).

Hilton (1988), using the phenomenological approach, described uncertainty as experienced by women diagnosed with breast cancer. Sixteen women who had been treated for breast cancer were interviewed using an open-ended format. Some women were newly diagnosed, while others had "survived" breast cancer as many as 25 years. Some women's cancer was localized, while others had systemic involvement. The experience of uncertainty for these women was not limited to any specific event or series of events, but rather had continued over time. The degree of uncertainty heightened from the time the lump was found to the present, and from day to day. Participants were constantly aware of their disease, felt unsure of the disease, and did not know what consequences were coming. Illness-related factors were identified as being associated with their level of uncertainty.

Loveys and Klaich (1991) explored experiences of breast cancer demands, from women's' own perspectives, by using both semi-structured interviews and questionnaires. The research question was "What is the impact of breast cancer on the daily lives of women during childrearing age?". Seventy nine women, newly diagnosed with breast cancer, were interviewed using a semi-structured format. The authors found 14 domains. Of relevance to this study are domains related to medical therapies, physical changes,

social interactions, uncertainty, acquiring new knowledge, making choices, and mortality issues. The study validated the complexity of the breast cancer experience.

Christman (1990) examined the relationships among uncertainty, medical therapies-related factors, control, and psychosocial adjustment. Various categories of cancer patients (n=55) who were within three months of diagnosis and who were receiving radiotherapy participated in the study. Patients were measured pre-radiotherapy, then 15 days later during therapy, and then in post-radiotherapy. Among all factors under consideration, uncertainty consistently explained the most variance in psychosocial adjustment (R^2 = .18 to .23 of .41).

In a descriptive study, Knobf (1986) interviewed and surveyed 78 women with breast cancer who also received chemotherapy for their breast cancer. The sample mean age was 51 years, 96% were Caucasian, and most in middle to high socio economic status (SES). Physical distress such as fatigue, loss of appetite, and nausea were rated between 1 to 2.5 on a scale of 1 to 5, with 1 indicating no distress and 5 indicating great distress. Psychological distress such as loss of the breast, dealing with diagnosis, and mood ranged between 1.5 to 4.5 on the same 1 to 5 scale. Diagnosis was perceived as the most distressful, followed by the categories *loss of breast* and *uncertainty of survival*. The women perceived more psychological distress than physical distress, even for women who completed chemotherapy.

Findings from both qualitative and descriptive studies are consistent. The most common themes are: experiencing breast cancer is stressful, uncertainty is ever present and perceived as distressful, and uncertainty may influence adjustment to illness and its treatment (Christman, 1990; Hagopian, 1993; Hilton, 1988; Knobf, 1986; Loveys & Klaich, 1991). Roberts, Cox, Shannon & Wells (1994) found that the women with breast cancer group scored one standard deviation above the mean on psychological distress than the non-cancer women group.

Health-care providers recognized that lessening patients' dysfunction through supportive care services is likely to benefit the patient in dealing with illness (Hagopian, 1993; Spiegel, 1990). The emphasis in supportive care services is upon quality of survival rather than survival alone. Supportive care services aim to assist patients in coping with their illness. Details of supportive care research were integrated into the literature review of the major categories: conditioning factors, proximal outcomes, and distal outcome.

Literature Related to Propositions of Conditioning Category

The conditioning variables of interest to this present study include personal characteristics, medical characteristics, mastery, and social support. Personal characteristics are demographic factors that existed prior to the SHIP interventions. Demographic factors include age and social economic status (SES).

<u>Proposition #1</u> - The relationship between Conditioning factors (personal, medical, social support, and mastery) and the Interventions.

The issue of self-selection by subjects and its influence on subjects' participation in treatment has been addressed by many authors (Horn, 1972; Labouvie, Bartsch, Nesselroade & Baltes, 1974; Siegler & Botwinick, 1979). Labouvie et al. (1974) examined the effects of selective dropout upon outcome changes of abilities in a stratified random sample of 1580 adolescents. Results indicate that volunteering behavior correlated with indices of outcome. Low-scoring persons tend to drop out; high-scoring persons remain. This ceiling effect can mask the treatment effect ,and can introduce bias, thus jeopardize the external validity of the study.

Likewise, in another longitudinal study that lasted nearly 20 years, Siegler and Botwinick (1979) found that attrition was selective and progressive. Namely, only persons scoring highly on the intelligence scale remained in the study. Conditioning factors such as personal characteristics can play a role in selective attrition from treatment group, and thus affect outcome changes differently.

Selection bias remains an issue in clinical trials. Most studies did and continue to draw subjects from convenience groups. Sampling frames are biased when clinical trials rely on referrals who are volunteers. Additionally, acceptance rates of subjects into studies are non-random. This problem is accentuated by the informed consent process and the meeting inclusion criteria process. For example, a lower referral rate from

teaching facilities may mean that sicker subjects are under-represented in the study. Besides volunteering to be in the SHIP study, participants were also referred to the project from many sites varying in size from small private clinic to large cancer center. Thus, selection bias was relevant to this study.

Proposition #2 - The relationship between Conditioning factors (personal, medical, social support, and mastery) and Proximal Outcomes (self-help, enabling skills, uncertainty, and psychological adjustment).

Personal Characteristics - Demographic factors such as SES have been documented as moderators of health-promoting behaviors (Mor, Allen, Siegel & Houts, 1992), psychological function (Andersen, 1993), and self-care (Albrecht & Nelson, 1993). In a breast cancer sample (n=135), Roberts, et al. (1994) reported that individual characteristics of people play an important role in the relationship between social support and personal adjustment to illness. Age has been reported as negatively correlated with distress (Vinokur, Threatt, Caplan & Zimmerman, 1989). Younger (<64 years of age) women perceived more distress from breast cancer than older women (>65 years of age). Cassileth, Lusk, Strouse, Miller, Brown, Cross & Tenaglia (1984) found a similar age-related adjustment pattern in subjects (n=758) with chronic illnesses (one of which is cancer).

The role of sociodemographic factors in the effectiveness of interventionswas described in Brown's (1992) report. Brown (1992) systematically reviewed both

published and unpublished intervention studies (n=73) related to treatment effectiveness in the arthritic population, and found that educational programs were more effective with younger patients.

Medical characteristics - Medical characteristics represent disease-related factors and therapy-related factors specific to the patient. As a whole, medical characteristics represent how ill patients are. **Disease-related** factors include cancer staging, presence of metastasis, and co-morbidity. Cancer staging refers to the extent of breast cancer found at time of diagnosis. Metastasis represents breast cancer as evidenced outside breast tissue at time of diagnosis. Co-morbidity refers to the number of other chronic illnesses which patients are experiencing concurrently. **Therapy-related** factors include primary therapy type and adjuvant therapy type. Primary and adjuvant therapies are medical therapies such as surgeries, chemotherapy, radiation therapy, hormone therapy, and hyperthermia therapy.

Disease-related factors such as cancer staging and metastasis have been documented as being meaningful moderators of health-related outcomes (Andersen, 1992; Gordon et al., 1980) and psychobehavioral outcomes (Andersen, 1993; Edgar, Tosberger & Nowlis, 1992; Ferrans, 1990; Lorig, Mazonson & Holman, 1993; Mor et al., 1992). In a sample (n=69) with various types of cancer, Andrykowski and Brady (1994) found that as much as subjects feel that they have control over events, their psychological

adjustment to cancer is moderated by their disease severity level and therapy-related history.

Findings concerning **therapy-related** factors are inconclusive. Taylor and colleagues (1985) examined the relationship between primary medical therapy types and psychosocial adjustment in 87 women with breast cancer. They found that the "more radical type of surgery" predicts poor psychological adjustment ($\beta = .40$, $F_{(1,64)}=13.96$, $p<.001$). Similarly, Maguire et al. (1980) found that patients receiving combinations of chemotherapy (n=26) had higher psychological distress ($p< .01$) than patients receiving single type chemotherapy (n=15) or patients with mastectomy only (n=18). On the other hand, some researchers suggest that neither type of primary medical therapy (Ganz, Schag, Lee, Polinsky & Tan, 1992; Kemeny, Wellisch & Schain, 1988; Lasry, et al., 1987) nor type of adjuvant medical therapy (Wallace, Priestman, Dunn & Priestman, 1993) adequately predicts how women will adjust psychologically.

Mastery - A number of investigators have examined the role of mastery also known as personal psychological resources (Roberts et al., 1994) in dealing with stress. One of the personal psychological resources that often has been examined is related to the individual's sense of control or sense of mastery. Mastery is the ability to behave in a way that can soften aversiveness to a situation (Pearlin & Schooler, 1978).

Others have defined mastery as the extent to which one imagines oneself capable of acting effectively on the environment to meet one's felt needs (Kobasa, Maddi &

Courington, 1981; Hobfoll & Walfisch, 1986). Persons who see themselves as able to control their own lives are less at risk i.e. for depression than individuals who feel helpless. Perceived control of events is the key element.

When confronted with a new stressor, persons with a sense of mastery or control over their environment will exploit their internal psychological resources to dissuade the resultant distress. For events that are appraised as threatening or uncontrollable, a sense of mastery is more likely to be employed in cognitive terms, whereby individuals may emphasize positive aspects of the situation.

In a convenience sample of 131 women with gynecological cancer, Mishel and Sorenson (1991) tested the relationship between mastery and uncertainty. Specifically, they tested the mediating function of mastery and concluded: 1) higher levels of uncertainty reduced the sense of mastery ($r = -.45$); 2) with mastery present, the proportion of variance in appraisal accounted for by uncertainty was reduced from 22% to 9%. According to the authors, the effect of uncertainty on appraisal is through mastery.

Mishel, Padilla, Grant and Sorenson (1991) replicated the above study and reported similar findings. In a sample of 100 women with gynecological cancer, more heterogeneous than the initial study, they found that mastery mediated uncertainty and appraisal. With both uncertainty and mastery entered into the regression equation, the beta level was reduced to .17, as compared to .27 with only uncertainty in the equation.

Interest in personal control and adjustment to cancer was studied by Edgar, et al. (1992). In a sample (n=205) with various types of cancer, patients were randomized into "early psychosocial intervention", "later psychosocial intervention", or control group. The authors found that patients with high perceived personal control had low levels of distress at baseline; for example, mean baseline score on depression of high personal control group was 9.52 as compared to 22.02 for the low personal control group. At 12 months into the study, the depression scores for these groups were 8.72 and 13.12 respectively, indicating little change for the high personal control group, but a significant reduction for the low personal control group. Thus, patients with high personal control had a lower distress level, and may not have needed or benefited from psychosocial intervention.

Although Mishel and Sorenson (1991) reported that uncertainty affects one's appraisal of an event mediated by mastery, it could be rather that one's uncertainty level is actually dependent on one's level of mastery. Thus, there is evidence that mastery plays a role in psychosocial adjustment to cancer, as well as responding to psychosocial treatments. This gives support to the proposed hypothesis in this study that treatment effects in improving subjects' uncertainty management or psychological adjustment is dependent on subjects' mastery or personal control level.

Social Support - Social support is another factor that has been postulated as influencing one's response to chronic illness (Viney & Westbrook, 1982). Studies

evaluating the relationship between social support and adjustment to stressors are very numerous. However, findings are not consistent, partly due to the complexity inherent in the concept of "social support", as well as how social support has been defined. Although the term "social support" is widely used, general agreement as to the definition of this term is lacking. Previous studies have typically conceptualized social support in two ways: social network size and functions, and perceived support. Social network refers to the social connections provided by the environment in terms of structural (size or density) and functional (provision of information, comfort, emotional support) dimensions.

Perceived social support refers to the impact networks have on the individual based on his/her subjective appraisal. Different types of social support may be valuable to cancer patients at different points in their disease process (Wortman, 1984). Tangible support may be of greatest importance to the physically debilitated patient, whereas emotional support may be more valuable during another disease stage.

Several studies have investigated the relationship between emotional support and adjustment in cancer patients. Bloom (1982) interviewed 133 breast cancer patients who had undergone surgical therapy within the preceding 30 months. The author found that perceived family cohesiveness and amount of social contacts were positively correlated with psychological adjustment. Similarly, others (Dunkel-Schetter, 1984; Funch &

Mettlin, 1982; Jamison, Wellisch & Pasnau, 1978) found that adjustment is correlated with patients' perceived support from others.

Adequate communication with significant others has been associated with facilitating patients' ability to deal with their illness (Funch & Mettlin, 1982). These findings are consistent with Ell's (1985-86) study in which perceived adequacy of support was found to be more predictive of positive outcome than availability of support.

Social network function was investigated by Zemore and Sheppel (1989). The authors assessed the effects of breast cancer and surgical therapy on emotional support and adjustment. Emotional support was defined as the ability of the subjects to talk with others about their situation. Through a central registry, the researchers solicited and enrolled 301 breast cancer patients and 100 women with benign breast lump into their study. Different from other studies, breast cancer women who were already receiving chemotherapy were excluded from the study. Patients were interviewed, and completed the self-administered questionnaires. The study found that cancer patients received more emotional support than women with benign breast lump ($F_{(1,382)} = 6.25$, $p = .01$). Emotional support in that study was positively correlated with self-esteem ($r = .27$) and adjustment ($r = .40$) in the women with breast cancer. This last finding was even more significant ($r = .36$ and $r = .67$ respectively) in the women with benign breast lump. Perhaps, having cancer or not having cancer is not the key factor, but rather the uncertainty level inherent in both diseases: breast cancer and benign breast

lump...because, to the women involved, benign lump may be a precursor to cancer. Mishel and Braden (1987) found that social support does not function to influence adjustment directly, rather social support affects adjustment through uncertainty.

In a detailed descriptive study of support, Stewart and colleagues (1995) interviewed patients with hemophilia and patients with Acquired Immune Deficiency Syndrome (AIDS), and their caregivers. The study was conducted in two phases: interview and mailed questionnaire. A total of 70 subjects participated in the study of which 30 were patients with AIDS. Similar to cancer patients, these AIDS patients identified inability to continue school or work as the most stressful factor. In relation to support, responses from both patients and care-givers indicated that understanding (63%) and affection (57%) were most valued as types of support. Family and friends were identified most frequently as sources of support. Finally, only roughly two out three subjects were satisfied with any kind of emotional, informational, or practical support available to them. Those who were not satisfied with their support perceived a need for services such as counseling, support group, and support from others in similar situations. This study upholds the need for structuring support as a component of psychoeducational intervention in supportive care services.

The relationship between social support and adjustment to breast cancer was investigated by Northouse (1988). Data were collected from 50 women with breast cancer, and from their husbands at three days and 30 days after surgery. Patients and

husbands who reported higher levels of social support also reported fewer adjustment difficulties with breast cancer.

Lastly, Fredette (1995) interviewed 14 women who had survived breast cancer an average of 13 years. Social support in the form of network size and of having relationships with others was cited as significant to 10 out of 14 women. Even years after being diagnosed with breast cancer, social support still played an essential role in their recovery from breast cancer.

In general and also in this study, social support is defined as nurturing/positive direct and indirect relationships which are believed to promote and enhance healthy functioning. Individuals with positive relationships are more likely to engage in positive health behaviors and practices; that is, social support moderates learning.

The relationship between social support and adjustment are evidenced in several studies. In life-related stress, studies have reported that social support makes a difference in stress and health (Cobb, 1976; Pilisuk & Parks, 1983). Being employed, having a social network, and perceiving helpful social support moderate the effect of interventions on outcomes (Andersen, 1992; Irvine, Brown, Crooks, Roberts & Browne, 1991; Lorig & Laurin, 1985; Rowland, 1989).

<u>Proposition #3 and Proposition #4</u> - The relationship between Conditioning factors (personal, medical, social support, and mastery) and Distal Outcome (well-being).

One's perceived 'well-being' depends upon personal characteristics, medical characteristics, social support, and sense of mastery. A number of investigators have examined the proposed relationships mentioned above. However, findings are fragmented and not clear or consistent.

Medical Characteristics. The influence of medical characteristics on perceived well-being was explored by McEvoy and McCorkle (1990). The authors determined that perceived well-being in patients with disseminated cancer is related to illness severity, specifically severity of symptoms. There is a clear pattern showing: the higher the illness severity, the lower the functioning level; the more dependent one is on others, the less well-being one perceives in self. They advocated that in order to improve patients' well-being, the first step of intervention should be focused on lessening severity of illness.

After agreeing to consider participation in a study, 104 cancer survivors three years past their last cancer treatment were surveyed (Schmale et al. 1983). Control subjects, subjects with no cancer, were matched from a pool of 1209 subjects for sex, age, and education. Medical therapy approaches were found to influence the 'well-being' scores of the cancer survivors ($t= 1.52$, 2-tailed $p=0.13$). Cancer survivors tend to have lower self-control or sense of mastery than healthy subjects (15.34 versus 16.29, $t=3.30$, 2-tailed $p< .001$). Additionally, cancer survivors perceived less 'well-being' than healthy subjects (13.95 versus 15.20, $t= 3.67$, 2-tailed $p< .001$).

Social Support. After reviewing the literature on well-being, Baltrush & Waltz (1987) and de Haes & van Knippenberg (1987) inferred that social support accounted for some variance in the indicators of 'well-being' in patients with various illness conditions. This relationship was also supported in a diabetes sample (Lundman, Asplund & Norberg, 1990) and organ transplant sample (Molzahn, 1991), but not in a breast cancer sample (Sidani & Braden, 1992; Roberts et al., 1994).

Although the relationship between social support and adjustment was not supported in Roberts et al's (1994) study, it is interesting to note that patients who scored high on Desirability Scale also reported high levels of support from others ($r = .42$). In addition, patients who scored high on Desirability also reported a lower level of psychological stress ($r = -.43$). Roberts et al. cautioned that high scores may indicate conscious distortion to create good impression, but it also may indicate high self-regard or perceived control. Thus, findings from this study are inconclusive. It is speculative that women high on Desirability may in fact cultivate more satisfying relationships, perceive more control, and thus feel less distress.

In a different type of population, environmentally stressed rather than illness stressed, Levitt, Clark, Rotton & Finley (1987) sampled 92 residents who were facing eviction from their homes. The authors found that perceived control predicted psychological adjustment ($\beta = .26$) and well-being ($\beta = .29$). Social support only predicted psychological adjustment ($\beta = .26$). Although the results were in accordance with the

study's hypotheses, support for the direction of the effects was not evidenced. It is possible that individuals, who are satisfied with their lives and maintain a higher level of positive mood, are more likely to form close relationships with others.

Mastery. A study related to mastery was conducted by Hobfoll and Walfisch (1986) wherein the relationship between mastery and depression as an index for emotional well-being was investigated. In a study with repeated measures, a non-random sample of 55 women with breast lump were interviewed prior to breast biopsy and then re-interviewed nine months later. Stressful events were significantly correlated with depression both at pre-biopsy ($r = .48$) and at a 9-month follow-up ($r = .44$) in subjects with the low mastery level. Whereas, this relationship was only significant ($r = .42$) at follow-up for subjects with high mastery level. Subjects with high mastery and experiencing low stressful events had the lower risk for depression (3.4 times) as compared to subjects with low mastery and experiencing low stressful events. Lastly, mastery was found to contribute significantly to risk for depression at both pre-biopsy ($\beta = .31$, $p < .05$) and follow-up ($\beta = .39$, $p = .01$).

Another study related to mastery (Edwards, 1991) found that individuals with lower level of mastery are more at risk. Studying the role of mastery in obtaining adequate prenatal care, Edwards inducted 102 low income women into her study. Mastery level was higher among those women who adequately obtained prenatal care in spite of obstacles similar to their counterparts.

The last study related to mastery, a correlational study, identified predictors of psychological well-being in elders (65 years or more) in nursing homes (Bowsher & Gerlach, 1990). Psychological well-being was indexed by Life Satisfaction Index and Affect Balance Scale. A convenience sample of 302 cognitively intact elders was screened for selection into the study. All instruments were administered orally during a private interview with each subject. Perceived control/mastery was found to be significantly correlated with ($r = .44$) and accounted for 19% of variance in psychological well-being.

Previous studies have suggested that medical characteristics, social support, and mastery are linked to life satisfaction or 'well-being' (Baltrush & Waltz, 1987; Bowsher & Gerlach, 1990; de Haes & van Knippenberg, 1987; Edwards, 1991; Hobfoll & Walfisch, 1986; McEvoy & McCorkle, 1990; Schmale et al., 1983). Evidence for the moderating effects has been elusive, however, emerging more clearly in some samples than in others. Nevertheless, it is likely that medical characteristics, social support, and mastery moderate as to how women would respond to psychosocial interventions.

Literature Related to the Propositions of Intervention Category

Breast cancer is a devastating and chronic illness characterized by an unpredictable course, with periods of severe illness from primary and adjuvant medical therapies. Like other chronic illnesses, breast cancer can have a great impact on quality

of life and perceived 'well-being'. Breast cancer not only affects physical functioning, but also affects social and psychological functioning.

Since breast cancer is infrequently cured, health-care providers are beginning to put more focus on supportive care. Currently, there is a push in health-care reform to inform consumers, and to achieve cost containment. Lessening patients' dysfunction through supportive care services, in addition to providing medical therapies, is likely to usefully benefit patients in dealing with their illness. The ultimate goal of supportive care is 'well-being'.

Supportive care services are designed to also meet patients' non-medical needs, which if left unmet may have adverse consequences on patients' 'well-being' (Yancik, Edwards & Yates, 1990). Those services come in several forms: behavioral support, informational support, psychological support, social support, and psychoeducational support.

Proposition #5 - The relationship between Intervention and Distal Outcome.

Proposition #6 - The relationship between Intervention and Proximal Outcomes.

Supportive care services in various forms (education, counseling, supportive, psychoeducational, etc.) have been tested. All types of interventions are reviewed for treatment effects in improving uncertainty management and self-help, improving coping skills and psychological adjustment, and enhancing 'well-being'. In a correlational study with 92 subjects, Mishel (1984) showed that uncertainty has a direct relationship to stress.

Uncertainty alone explained 22% of variance in stress. Thus, interventions focused on improving patients' uncertainty management skills would be expected to also reduce patients' perceived stress.

The self-efficacy gained from an individual psychological program in support of quality of life and psychological adjustment was studied by Greer et al. (1992). Prospective randomized controlled design was used, and data were collected at pre-treatment, post-treatment, and four-month follow-up. A program of psychological therapy and problem focused/cognitive behavioral therapy was designed to meet individuals' needs. The authors inferred that psychological intervention produced significant improvement (12% reduction from baseline) in psychological distress among cancer patients (n=156).

Emotional coping of persons newly diagnosed with cancer was evaluated by Edgar, et al. (1992). Subjects were randomized into early intervention (n=103, 10 weeks after diagnosis) or late intervention groups (n=102, 26 weeks after diagnosis). The intervention aimed to promote problem solving, goal setting, cognitive reappraisal, relaxation, and effective use of resources. No difference was found between the two groups, except at the eighth month follow-up in which the late intervention group was found to be less depressed and anxious. This point emphasizes the need for longer term follow-up data collection than post-test alone.

The effects of a professional support group on psychological adjustment in women with metastatic breast cancer was investigated by Spiegel, et al. (1981). Fifty-eight women were randomly assigned to a support group and a control group. Participants were followed at four month intervals over a one year period. Despite a report of positive results from the intervention, conclusions are far from definitive, due to high attrition rate (52%), small sample (treatment group n=34 and control group n=24), non-standardized treatment format, and questionable statistical techniques used.

Other studies have reported positive results with group support interventions on psychological adjustment in patients with newly diagnosed or advanced breast cancer (Cain, Kohorn, Quinlan, Latimer & Schwartz, 1986; Jacobs, Ross, Walker & Stockdale, 1983). Overall, behaviorally oriented programs involving training in active goal setting and stress reduction methods have shown better results than purely supportive interventions (Cunningham & Tocco, 1989; Telch & Telch, 1986).

Lemaire and Lenz (1995) reported that an educational program which aimed to increase participants' (n=173) knowledge related to menopause had a positive effect. The authors determined that the more knowledge the participants gained from the intervention, the less uncertain they become ($p<.001$). Interpretation of this study's findings is limited due to the use of the one-group pretest posttest only design.

Dodd (1983) randomized a sample of 48 patients with breast cancer into four groups. Three groups received illness-related information, and one did not. There was a

significant difference in self-care performance scores between those who received information versus those who did not [$F(1,44)=7.60$, $p<.01$]. Dodd's findings support the hypothesis that effective self-care behaviors can be learned. Further, Grassman's (1993) study revealed that education classes related to personal symptoms management were viewed as particularly useful to subjects with cancer.

A meta-analysis by Devine and Westlake (1995) reviewed 116 studies, and found psychoeducational interventions to be beneficial to adults with cancer, with regard to emotional depression ($d= .54$), mood ($d= .45$), and knowledge ($d= .90$). Upon further examination, the author identified the need for examination of specific components of psychoeducational interventions.

The individual versus group intervention issue was addressed by Brown (1992) who suggested that an individual approach, rather than group approach, was most effective for improving outcomes. The merit of balancing between the cost-effective group approach and the more costly but more effective individual approach needs further investigation.

Glasgow, Toobert, Hampson, Brown, Lewinsohn, and Donnelly (1992) were interested in testing different components of an intervention. Using the waiting-list control design, 78 diabetic patients were stratified by sex and mode of medical therapy, then randomly assigned to three groups: education only (E) ($n=28$), education and behavioral learning (EB) ($n=28$), and control group ($n=22$). The educational component

aimed to increase participants' knowledge about nutrition as related to diabetes. The EB component received the educational intervention as well as lessons regarding goal setting and problem solving. The control group received conventional care. Although the findings did not support one component over another, this study underscores the importance of investigating treatment effectiveness relative to its components rather than as a whole.

Cunningham and Tocco (1989) randomized self-referred subjects with various types of cancer into a psychoeducational group (n=30) versus a supportive (n=30) group. In general, subjects in the psychoeducational group did slightly better than the supportive only group ($t= 2.01$, $p =.05$) in the category of mood disturbances. It is difficult to determine from this study whether the treatment was actually effective. On the one hand, the treatment effect may have been inflated merely because intervenors were also personally involved in the research project, creating the problem of.experimenter expectancy (Campbell & Stanley, 1966). On the other hand, treatment effects could have been diluted due to nonspecificity of treatment protocol, heterogeneity of sample (lung cancer, colon cancer, breast cancer, and melanoma), short follow-up (2 weeks), use of global outcome measure (mood), and small sample size of completers (n=28 and 25). This study illustrates the need for intervention studies with strong design, i.e. testing of treatment components, treatment strength, dosage-response, and outcome process.

<u>Proposition #7 -</u> The relationship between Intervention and Distal Outcome (well-being) with Proximal Outcomes acting as a mediator.

Knowledge or counseling alone (Maguire, et al, 1981) is insufficient for initiating and sustaining change, whether it is behavior or attitude related. Singular approaches to education and support are often merged to create a new approach: the psychoeducational approach. Psychoeducational interventions are designed to supplement medical therapies and to promote adaptation to chronic illness by increasing the person's resources and control over illness-related situations. The psychological segment of psychoeducational interventions addresses the psychological aspect of living with chronic illness in such areas as uncertainty management and adjustment. The educational segment of psychoeducational interventions addresses the cognitive aspects of living with chronic illness in such activities as learning new skills, learning new behaviors, or learning about the illness.

Lenker, Lorig and Gallagher (1984) determined that patient education did not directly change health behavior or health status. In further exploration, Lorig and associates concluded that self-efficacy mediates the effect of self-management intervention on pain (Lorig, Seleznick, Lubeck, Ung, Chastain & Holman, 1989). In a later study (n=127), Lorig and Holman (1993) found that a 19% reduction in pain was accounted for solely by the Arthritis Self-Management Program (ASMP). This reduction is separate and beyond the pain reduction by medications which usually claim credit also

for about 19%. Although Lorig's clinical randomized trial examined the treatment duration (4 years after intervention) and process of ASMP, it lacks examination of treatment strength. Self-efficacy, a mediator of patient education on health status outcomes, is also echoed by Taal, Rasker, Seydel & Wiegman (1993).

Although many clinical trials have supported the effectiveness of the self-management/behavioral approach, the majority of these studies were only interested in demonstrating "input/treatment" causes "output/outcome" (Gilden et al., 1992; Glasgow et al., 1992; Massouh, Steele, Alseth & Diekmann, 1989).

Most of the studies were limited to one follow-up measurement and assessment an average of four months after intervention (Massouh, et al., 1989; Greer et al., 1992), or two years after intervention (Gilden et al., 1992). Many clinical trials were limited to small samples (Hobfoll & Walfisch, 1986; Strauss et al., 1986). In addition, numerous studies had no control group, lacked standardized intervention, discounted individual variations (Greer et al., 1992), inappropriately used statistical analysis (Greer et al., 1992; Levitt et al., 1987), or were atheoretical (Gilden et al., 1992).

Literature Related to Propositions of Proximal Outcomes Category

Proposition #8 - The relationship between Proximal Outcomes (self-help, enabling skills, uncertainty management, and psychological adjustment) and Distal Outcome (well-being). The relationship among Proximal Outcomes of self-help, enabling skills, uncertainty management, and psychological adjustment.

The effects of uncertainty and adjustment on chronic illness have been less frequently studied due to the relatively new formulation and acceptance of the concept "uncertainty" in health-related fields. Braden's (1990a, 1993) earlier work assessed relationships among severity of illness, uncertainty, enabling skills, self-care, and well-being in a convenience sample of 288 arthritic patients. The findings suggested that severity of illness is a strong predictor of uncertainty (β=.62), and that uncertainty has a direct effect (β=-.16) as well as indirect effect on perceived 'well-being' gained through enabling skills.

The relationship between self-confidence, social support, and well-being was investigated by Dirksen (1990). A convenience sample of 75 subjects with melanoma was studied. The author reported: social support moderately predicts self-confidence (β=.27), which in-turn strongly predicts perceived well-being (β=.49) in women with cancer.

The impact of breast cancer on subjects' physical and psychological well-being was examined by Hughes (1993). A convenience sample of 52 women newly diagnosed with breast cancer was used with data collection points: prior to medical therapy selection, and eight weeks after primary medical therapy. The findings indicated that subjects' perceptual uncertainty worsened, while psychological well-being was unaffected.

Literature Related to Propositions of Distal Outcome Category

As related to Distal Outcome, it is proposed in the present study that "observed" change in perceived well-being is attributable directly to intervention variables (**c**), proximal outcome variables (**b**), conditioning variables (**l**), and the interaction effects of these variables (**j**, **k**, **m**, **a**).

Adjustment to chronic illness has been measured by affective mood, ability to care for self, and ultimately patients' perceived 'well-being'. Well-being, in general and in health-related areas, represents satisfaction with needs in various dimensions: physical, psychological, and social. Thus, 'well-being' is subjective and individualized (Campbell, Converse & Rodgers, 1976; Diener, 1984).

'Well-being', as conceptualized here, is methodologically problematic. Measurement issues include 1) use of global versus multidimensional instruments; 2) inclusion of disease-specific items versus health-related items; and 3) use of generic measure versus disease-specific measure (Aaronson, 1991). Other methodological issues are 1) length and format of measurement; 2) time frame for measurement; 3) scaling method; and 4) influence of current mood on response. Individuals tend to perceive situations in a way congruous with their current affect or mood (Diener, 1984). To overcome these limitations, longitudinal design has been recommended (Yancik et al., 1990), but attrition over time restrains statistical power, not to mention the inability to study well-being during exacerbations and advanced disease stage.

Contrary to the belief that 'well-being' decreases with aging, 'well-bein' is stable across age (Carp & carp, 1983). 'Well-being' is relative to the individual's current values and expectations (Diener, 1984; Palmore and Kivett, 1977). Even though elderly individuals' functional capacity may be decreased, or their mobility levels may be limited, their perceived 'well-being' is adjusted according to their current capabilities. Therefore, regardless of time or aging, perceived 'well-being' can be sensitively measured by the use of self-anchoring scaling (Diener, 1984; Palmore and Kivett, 1977).

In addition to personal characteristics, medical characteristics, social support, and mastery (as discussed earlier), other factors were found to influence perceived 'well-being'. Ability to care for self had a strong positive effect (B=.62) on perceived 'well-being' in patients with arthritis (Braden, 1990a; 1990b). 'Well-being' in long-term cancer survivors was investigated by Ferrell, Dow, Leigh, Ly & Gulasekaram (1995). Members of the National Coalition for Cancer Survivorship (NCCS) with various types of cancer were surveyed by mail; of 1200 surveyed, 687 members responded. Personal characteristics such as marital status and income had significant influence on perceived 'well-being'.

In sum, prior theoretical propositions and empirical findings lend support for testing the hypotheses put forth in this study. Factors related to substantive factors, methodology, and the treatment itself influence outcomes. Substantive factors including personal characteristics, medical characteristics, social support, and mastery can modify

one's response to SHIP interventions. Methodological factors included lack of theoretical framework guiding the design and implementation of treatment. Lacking in the current literature are "process" studies. Lastly, treatment factors included "packaged", non-specific treatment components, and un-quantifiable treatment strength.

Summary

Chapter two described the theoretical framework of this study. The explicit framework in this study is an integration of substantive theory along with treatment theory.

Substantive theory is the theoretical structure of a study i.e. an intervention; it provides theoretical guidance in the design of the intervention. Substantive theory, derived from Braden's Self-Help Model, holds that if a person's repertoire of skills is enhanced, and if the person feels less uncertain about the illness experience, then that person's well-being will therefore be better. Treatment theory provides the link between concepts or steps, using variables of substantive theory to explicate treatment process patterns. Underlying assumptions related to patient, health, chronic illness, and change were presented.

Relationships among conditioning variables, interventions, proximal outcomes, and distal outcome were proposed in general and specifically. Conditioning variables of interest to this present study include personal characteristics, medical characteristics, mastery, and social support. Psychoeducational interventions, based on the Self-Help

Model (Braden, 1990), being evaluated in this current study include: 1) self-help independent study (SHIS); 2) self-help class (SHC); 3) uncertainty management (UM); 4) combination of SHIS and UM, and 5) combination of SHC and UM. The proximal outcomes of interest in this study are: 1) self-help; 2) enabling skills; 3) uncertainty management, and 4) psychological adjustment. The distal outcome of interest in this study is patients' perceived state of 'well-being.

Review of the literature included 1) the cancer experience; 2) hypothesized relationships concerning conditioning variables; and 3) the effects of various types of supportive care interventions related to proximal outcomes and distal outcome variables in patients. Lastly, limitations of the study's theoretical framework were delineated.

CHAPTER III

METHODOLOGY

This chapter begins with a discussion of the study's research design. Following are discussions of criteria for inclusion, human subjects' protection, the sample, and the setting. Next is a discussion of the instrumentation, including measurements for 1) the conditioning variables, 2) the treatment variables (independent variables), 3) the proximal outcome variables, and 4) the distal outcome variable. Data collection procedures, specific hypotheses to be tested by this study, and the data analysis plan are presented. Finally, the study's limitations are explained.

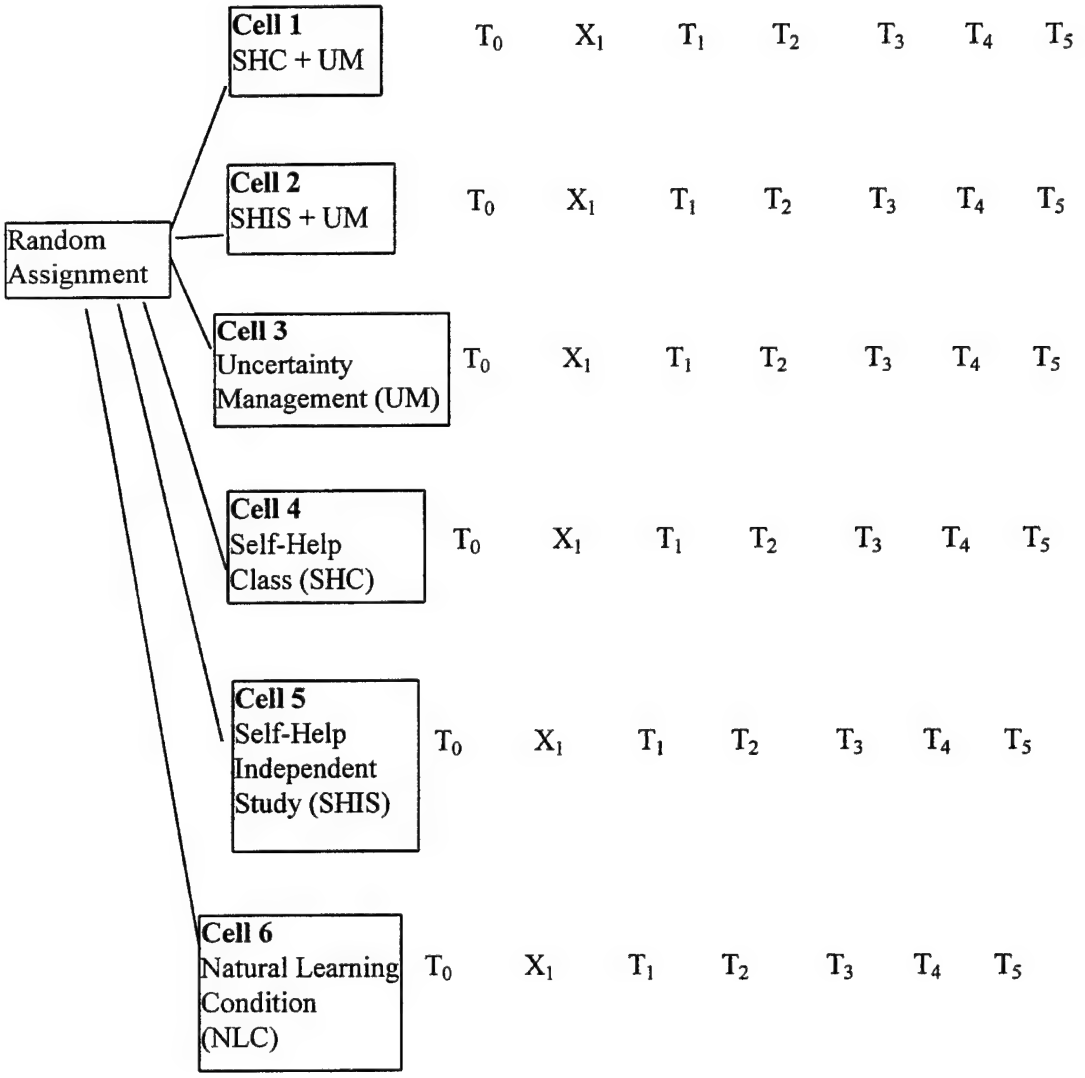
Research Design

This study utilized secondary analysis of data from the original Self-Help Interventions Project (SHIP). The design of the SHIP study was experimental using random assignment with repeated measures (Braden, Mishel, Longman, & Burns, 1988) (Figure 3.1). This secondary analysis study extended the SHIP study by testing for a comprehensive set of hypotheses related to treatment effectiveness and treatment strength of the SHIP interventions.

Criteria for Inclusion

Several criteria for inclusion were imposed in selection of the subjects for this study in order to control for extraneous variables, and to increase sample homogeneity. The selection criteria included:

Figure 3.1. Research Design



1. age 18 or older;

2. able to read and write English;

3. concurrently receiving adjuvant therapy for either primary or recurrent breast cancer, including any or combination of the following: chemotherapy, radiation therapy, hormone therapy, and hyperthermia treatment; and

4. free of psychopathological symptoms such as diagnosed major depression. Having psychopathological alterations will interfere with learning, perhaps perception of events, and performance of self-care activities, all of which may confound the expected outcomes.

Human Subjects' Protection

The university Institutional Review Board (IRB), located in a southwestern state of the United States, approved the SHIP project and exempted it from review (**Appendix A**). This secondary data analysis study entitled "Evaluation of the Self-Help Interventions Program (SHIP): Psychoeducational Interventions for Patients with Breast Cancer" was submitted for review by the University Ethical Review Committee (**Appendix B**).

All subjects were informed of details related to the benefits, costs of involvement, and the goal of the study. Subjects were identified and solicited by key clinical personnel and consented to participate in the SHIP project. Advertising recruited some volunteer subjects.

All collected personal data are kept confidential. Subject code numbers of participants were used in order to maintain anonymity. Other subjects' identification information is kept separate from the data. Use of study data is limited to only the collaborative research team and staff. The data are kept secure.

Sample and Setting

Women who were receiving adjuvant therapy for breast cancer were recruited by field workers for the SHIP project from multiple clinical treatment sites, as well as community entities throughout a city in a southwestern state. Recruitment from clinical treatment sites was primarily from regional cancer care centers, private practices, and health maintenance organization clinics. Recruitment by advertisement came from community sites such as libraries, hair dressers, retail stores, recreational facilities, and media announcements. Participants were recruited from January 1990 through March 1992.

Women who expressed interest in learning more about the study were contacted by telephone. Of those 519 women who were initially contacted, 482 met the inclusion criteria. Of those who met the criteria, 175 declined to participate in the study (36.3% refusal rate). Refusers were defined as women who declined to enter the study after being contacted by telephone, and those who agreed to participate in the study but did not complete baseline data collection or enter into intervention at baseline and thereafter. Reasons for refusal offered most in the order of frequency were 1) no interest/need

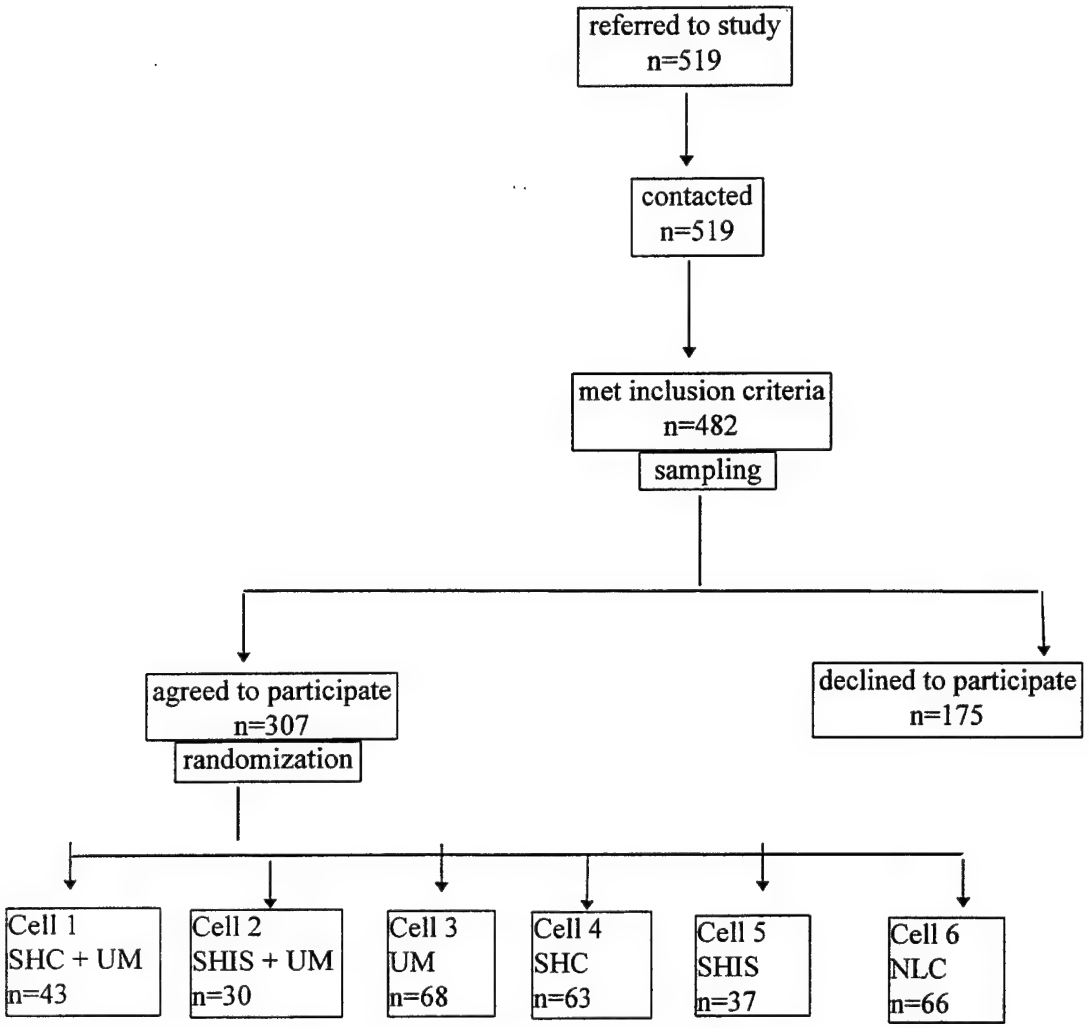
(n=88/74); 2) too busy (n=43/34); 3) too far (distance) (n=27/23); 4) too ill (n=23/13); 5) lack of transportation (n=17/16); 6) too old (n=7); 7) expense (n=2); and 8) others such as husband needs care, other illnesses, and overwhelmed (n=36). Enrollment in the SHIP study was voluntary, thus the sampling was nonprobability based.

Once having consented to participation, the women were randomly assigned to either the natural learning condition (Cell 6) or one of the five interventions: Cell 5 - self-help independent study lessons (SHIS); Cell 4- self-help classes (SHC); Cell 3 - uncertainty management provided by a nurse client manager (UM); Cell 2- combined of SHIS and UM; and Cell 1 - combined SHC and UM (Table 3.1). The sample for the SHIP study and this study consisted of 307 women who had undergone primary treatment for breast cancer. The sampling process is summarized in Figure 3.2.

Table 3.1. Group Assignment and Subjects per Group Cell.

	Self-Help Independent Study	Self-Help Class	Uncertainty Management
Nurse Case Manager	Cell 2 (n=30)	Cell 1 (n=43)	Cell 3 (n=68)
Natural Occurring	Cell 5 (n=37)	Cell 4 (n=63)	Cell 6 (n=66)

Figure 3.2. Sampling Process of the Self-Help Intervention Project (SHIP)



Legend:
NLC = Natural Learning Condition
SHIS = Self-Help Independent Study
SHC = Self-Help Class
UM = Uncertainty Management

Instrumentation

A total of 11 instruments were used to assess the efficacy and effectiveness of the SHIP interventions. Instruments used in this study are included in **Appendix C**. Following are the descriptions and the measure of four conditioning variables, five independent variables, four proximal outcome variables, and one distal outcome variable.

Within each section, when appropriate, a description of procedures for using the instrument/measure, and scoring of the instrument is presented. Included are reliability and validity assessments. Lastly, selected instrumentation issues were explored.

Conditioning Variables:

Personal Characteristics, Medical Characteristics, Mastery, and Social Support

The conditioning variables are defined as any variable that potentially can moderate the effect of the independent variable/treatment upon the outcome, as well as correlate with the treatment being studied (Chen & Rossi, 1987; Costner, 1989; Finney & Moos, 1989). These variables can obscure the benefits of the intervention. In this study, personal characteristics and medical characteristics are proposed to potentially affect one's participation in the SHIP intervention. Additionally, personal characteristics, medical characteristics, initial status of mastery, and initial status of level of social support are theorized as having the potential to affect the treatment's outcome.

1. Personal Characteristics. Personal characteristics such as age and were surveyed in the Demographic Form (DEM).

2. Medical Characteristics. Medical characteristics, disease-related and therapy-related, were surveyed in the DEM.

3. Mastery. Mastery level was measured by the Mastery Scale (MS). The MS (7 items) estimates the efficacy level (i.e. belief in one's self) as capable of overcoming adversities (Pearlin & Schooler, 1978). The item uses a 100mm visual analog scale, and is anchored by "strongly agree" and "strongly disagree". The MS was designed for self-administration. The items are scored in a positive direction; the higher the score the higher mastery one has. Mishel, et al. (1991) reported an alpha coefficient of .73 in a sample of 100 women with gynecological cancer. Test-retest reliability has been estimated at .84 (Hobfoll & Walfisch, 1986). Standardized Item Alphas of Mastery Scale for SHIP were .82, .81, and .87 for measurement at time 0, time 1, and time 2 respectively. Concurrent validity of MS is supported by the positive relationship between mastery and self-esteem (Pearlin & Schooler, 1978).

4. Social Support. The variable of social support was indexed using the Arizona Social Support Arizona Social Support Interview Schedule (ASSIS).

Arizona Social Support Interview Schedule (ASSIS). The ASSIS (42 items) surveys the perceived network size, actual utilization of the network, satisfaction with the received support, and support needs (Barrera, 1980). There also were subscales to address need, use, and satisfaction, with six items for each category. The scoring for ASSIS is complex and was designed to be used in an interview, rather than to be self-administered. A

higher score on ASSIS indicates higher level of social support. Test-retest reliability is estimated at .80 (Barrera, 1981). For SHIP, Standardized Item Alphas of ASSIS was .83, .84, and .83 for measurement at time 0, time 1, and time 2 respectively. Table 3.2 summarizes the scales, its Cronbach alpha coefficients, and type of validity for each scale's performance in prior studies. A copy of each of the above scales can be found in **Appendix C**.

Table 3.2. Instrumentation for Conditional Variables.

Variable	**Instrument/Measure**	**# of item & format**	**Estimated Reliability**	**Validity**
Personal Characteristics	Demographic Data	Checklist	N/A	N/A
Medical Characteristics	Demographic Data	Checklist	N/A	N/A
Mastery	Mastery Scale	7 items VAS	α= .73	Concurrent (Pearlin & Schooler, 1978).
Social Support	Arizona Social Support Interview Schedule (ASSIS)	42 items	α= .89	Criterion (Barrera, 1981).

Note: N/A = not applicable

Independent Variable: SHIP Interventions (Self-Help Independent Study, Self-Help Class, Uncertainty Management, Self-Help Independent Study and Uncertainty Management, and Self-Help Class and Uncertainty Management)

The independent variables in this study are the SHIP interventions. The SHIP interventions, as a whole, were formulated using the Self-Help Model (Braden, 1990b). The SHIP interventions have essentially two basic components: self-help information and management of uncertainty. Singularly and combined, these components make up five SHIP interventions. They are 1) Self-Help Independent Study; 2) Self-Help Class, 3) Uncertainty Management, 4) combination of Self-Help Class and Uncertainty Management, and 5) combination of Self-Help Independent Study and Uncertainty Management.

Based on the evaluative framework of this study, the treatment aspects evaluated in this study are components within SHIP interventions and strength of each component. Each SHIP's component, its specifications, and its measurement of strength are presented sequentially and summarized in Table 3.2.

1. Criterion of the Self-Help Independent Study (SHIS) Component (Table 3.3).

The SHIS component was based on Braden's middle range theory of learned response to chronic illness (Braden, 1990a; 1990b). The activities in the SHIS were structured to enhance patients' problem solving skills, cognitive reframing, self-belief skills, and breast

cancer information. Thus, the SHIS component focuses on cognitive and behavioral aspects.

All subjects (N=37) randomly assigned into this group received a standardized self-study workbook. At baseline (T_0) data collection, the subjects were explained the details regarding the Self-Help self-study course which included experiencing six weekly lessons. These lessons were designed to be completed by subjects, without assistance and at their own pace. Each lesson was estimated to take an average of 90 minutes to complete. Upon completion of each lesson, subjects were asked to complete and mail the evaluation of that particular lesson. The evaluation form served as a means to identify whether or not subjects completed the lessons, as well as a measure of perceived helpfulness provided by each lesson.

Measurement of SHIS Component Treatment Strength. First, the treatment strength for the SHIS component was rated according to the indicators (Table 3.3) as specified by (Sechrest & Yeaton, 1981). Of all six indicators identified in Table 3.3, only **purity**, **frequency**, and **intensity** can be varied.

A panel of experts (n=5), who had background in oncology, interventions research, and program evaluation, was asked to rate the treatment strength according to the criteria spelled out by Sechrest and Yeaton (1981). Treatment strength of SHIP was quantified according to purity, frequency, and intensity, as well as preparation and

education level of intervenor. Criteria for quantification of SHIP treatment strength is included in **Appendix D**. Eighty percent (4 out of 5) was used as criteria of agreement.

Experts were asked to weight indicators, as well as the degree to which each indicator was met. For example, having protocol (purity), as opposed to no protocol, may be weighted more than whether or not subjects completed all six lessons (intensity). A second weighting is the level at which each indicator was met, i.e. subjects who completed all six lessons would have stronger treatment than subjects who only completed three or four lessons.

Secondly, the Level of Helpfulness of the independent study lesson to the subjects was captured by the Self-Help Activity Rating Scale (SHARS). The SHARS measures the perceived level of utility of each treatment activity within the independent study lessons. Participants were asked to rate each study lesson on how helpful the activities were to them. The SHARS consists of six multi-item rating sheets, one for each lesson. Each item is linked to a treatment activity offered for each self-study lesson. Each activity was rated on a three-point response format: 1 = did not help; 2 = helped some; and 3 = helped a lot. A total score for each class session was computed as the sum of all the item responses. A high score indicates that the activities were helpful to the participant. The helpfulness and satisfaction levels were used to measure the effectiveness of the specified SHIS intervention.

Table 3.3. Indicators of Strength of the Independent Variable: SHIP Interventions and Its Components

Indicators	**Self-Help Independent Study (SHIS) Component**	**Self-Help Class (SHC) Component**	**Uncertainty Management (UM) Component**
specificity	cognitive, behavioral	cognitive, behavioral	psychological
purity	use of standardized workbook	use of standardized teachers' guide or protocol	use of standardized assessment/intervention guide or protocol
potency	N/A	teacher's level of education	manager's level of education
duration	six weeks	six weeks	six weeks
frequency	self-study at own pace	one session per week average session: 90 minutes	minimum of one phone contact per week average phone contact: 20 minutes
intensity	proportion of lessons completed	proportion of classes attended	number of phone contacts % of problem solved

Note: The same criteria will be used for the combination interventions (SHIS/UM and SHC/UM)

2. Criterion of the Self-Help Class (SHC) Component (Table 3.3). The SHC component is the same as the SHIS component, except the SHC component was delivered to the subjects by trained teachers. Group members also interacted as participants learned with one another and with the teachers. Thus, the SHC component was also focused on the cognitive and behavioral aspects of psychoeducational interventions.

Over the project period, a total of six trained teachers conducted the SHC component of the SHIP intervention. Teachers included four nurses, a social worker, and a counselor. The SHC component consisted of six consecutive weekly classes of 60 to 150 minute class protocols. The protocols were: 1) delivered by trained teachers to subjects; 2) employed a standardized teachers' guide with a script and time allocation for each lesson (Table 3.4); and 3) . Class sessions were audiotaped to monitor for adherence to protocol.

The Self-Help classes were held on Saturdays at the College of Nursing, University of Arizona, with convenient parking available. A pre-arranged classroom to accommodate up to 10 subjects was used, and when possible the same classroom was used. The seating arrangement was circular to facilitate group discussion and exchange of ideas among participants.

Measurement of SHC Treatment Strength. Treatment strength of the SHC component was indexed as mentioned in the above SHIS component. Not all subjects in the SHC intervention group attended all six classes, as expected. Treatment strength for this intervention was measured by the proportion of SHC that the participants had attended.

Additionally, the participants were asked to rate each class session on 1) how helpful the activities were to them, and 2) how satisfied they were with the SHC and the

trained teachers. This Level of Helpfulness was indexed by Self-Help Activity Rating Scale (SHARS). The SHARS consists of six multi-item rating sheets, one for each class.

Table 3.4. Self-Help Independent Study and Self-Help Class Protocol

Time	Activities	Examples
150 minutes	belief in self	use of relaxation exercises use of resources share strategies that work confidence in breast cancer knowledge
120 minutes	problem solving	"Color Me Treated" "Maintaining Social relationships - Asking for Help" "Your Relationship with Health Care Providers"
120 minutes	cognitive reframing	recognize communication pattern able to do positive versus negative self-talk
90 minutes	breast cancer knowledge	breast cancer disease characteristics breast cancer treatment options disease variability and treatment match resources for finding medical treatment protocols
60 minutes	miscellaneous	introductions, breaks, and evaluation

Each item is linked to a treatment activity offered during the class. Each activity was rated on a three-point response format: 1 = did not help; 2 = helped some; and 3 = helped a lot. A total score for each class session was computed as the sum of all the items responses. A high score indicates that the activities were helpful to the participant. The helpfulness and satisfaction levels were used to measure the strength of the SHC intervention.

3. Criterion of the Uncertainty Management (UM) Component (Table 3.3). This intervention and its standardized assessment-intervention interactions between the nurse client managers and participants were guided by Mishel's (1988; 1990a) theory on uncertainty of illness. The activities of UM intervention were centered around 1) introducing and enhancing strategies for managing the uncertainties that are inherent in the experience of breast cancer, 2) providing necessary information, and 3) promoting self-care. Thus, UM intervention illustrates the cognitive and psychological components of the SHIP study.

Nurse client managers, who had a background in oncology and mental health, spent an average of 20 minutes on the phone with each of the subjects weekly for six weeks. Additionally, the participants were invited to contact the assigned nurse client manager to discuss emerging problems...few did. A total of four trained nurses delivered the UM intervention during the entire SHIP study.

The subjects were contacted by the nurse client manager at home during the day or evening. Phone calls were made from a private office which was housed in the College of Nursing, University of Arizona, in order to maintain privacy. Phone transactions were audiotaped and fieldnoted to monitor adherence to protocol.

The process of UM intervention implemented by the nurse client managers was as follows:

1. explored the participants' concerns/problems related to treatment and uncertainties. Listing of problems was then catalogued on computer, and followed-up during the next phone contact.

2. assessed the participants' levels of uncertainty. Uncertainty was defined as any situation when events occurred above and beyond the participants' expectations related to duration, intensity, frequency, number, and location.

3. inquired about the participants' estimation of the meaning of the identified uncertainty. Uncertainty can be judged as either a danger or as an opportunity for growth. implemented activities that were most likely to relieve the perceived uncertainty. The intervention was then catalogued in the computer for subsequent phone contact, and served as a basis for reassessment and determination of resolved problems. In general, these activities were designed to:

- strengthen an existing cognitive, or reinforce existing appraisal of uncertainty as an opportunity to grow, i.e. reinforce the participants' coping strategies, validate the participants' self-care behaviors;
- promote cognitive structure formation, i.e. provide related information necessary for decision making;
- reduce inappropriate negative perceptions, i.e. promote an opportunistic view of the situation;

- regulate emotional response, i.e. encourage positive self-talk, ventilate feelings, selective use of humor; and
- manage continual certainty, i.e. enhance personal control, generate multiple options, reframe the uncertain situation into a common familiar situation.

Measurement of UM Treatment Strength. Treatment strength of Uncertainty Management component was captured by four means. Because the phone contacts were specific to each participant, the strength of the UM intervention was gauged in each specific case with the **number of telephone contacts** between the nurse client mangers and the participants. Additionally, treatment strength of SHC intervention was also captured by measures of **level of satisfaction** by using a nine items of Access to Nurse Case Manager (ANCM) questionnaire The total ANCM, 27 items, was designed to measure accessibility to nurse-client manager and satisfaction with nurse-client manager and UM intervention. The ANCM uses a dichotomous format, as well as five point Likert scale anchored by not satisfied (1) to extremely satisfied (5).

4. Combination of Self-Help Class and Uncertainty Management (SHC and UM).

The subjects in this intervention group received both lessons from Self-Help classes for six weeks, and concurrently received the six 20-minute contacts from the nurse client manager.

Measurement of SHC and UM Treatment Strength. The strength of this combination intervention is based upon combined measures of Self-Help Class and Uncertainty Management interventions.

5. Combination of Self-Help Independent Study and Uncertainty Management (SHIS and UM). The subjects in this intervention group received both the self-study lessons, and concurrently received the six 20-minute contacts from the nurse client manager.

Measurement of SHIS and UM Treatment Strength. The strength of this combination intervention was based upon the combined measures of Self-Help Independent Study and Uncertainty Management interventions.

6. Natural Learning Condition Group or Control Group (NLC). The subjects in this group were free to find and receive information related to: breast cancer treatment, treatment effects, coping, etc. on their own and at their own pace.

Measurement of NLC Treatment Strength. Subjects were monitored, parallel to the treatment group, for six weeks. Treatment strength for the NLC is the degree to which the subjects received help/information from the standard/conventional way. Data related to: 1) where they received information/help, 2) from whom they received the information/help, and 3) whether or not the received information was useful to them. Treatment strength for the control group was captured by measures of **level of satisfaction** by using the six items of Control Group Questionnaire (CGQ). The CRQ

(six items) was designed to measure accessibility to routine care and satisfaction with the care they had received. The CGQ uses a five point Likert scale format anchored by not satisfied (1) to extremely satisfied (5).

Proximal Outcome Variables:

Uncertainty Management, Psychological Adjustment, Enabling Skills, and Self-Help

Proximal outcomes are outcomes that are theorized as being affected immediately by the treatment. The affects of treatment on outcome are indirect. Proximal outcomes represent the mechanism or process through which the treatment is presumed to have its affect on the outcome. Proximal outcomes, also known as "treatment construct" (Costner, 1989), or mediators (MacKinnon, 1996), to be evaluated in this study include: uncertainty management, psychological adjustment, enabling skills, and self-care.

1. Uncertainty Management. This variable was indexed by Mishel's Uncertainty in Illness Scale (MUIS).

Mishel's Uncertainty in Illness Scale (MUIS). The MUIS, 33 item scale, estimates the degree to which participants are not able to assign meaning of illness related events (Mishel, 1981). The items use a 100mm visual analog scale, and are anchored from "true about me" to "not true about me". Scoring is in a positive direction for uncertainty. The higher the scores, the more uncertain the participant feels. Reliability of the total scale by internal consistency in a cancer population was estimated at .91. Mishel

(1990b) reported convergent validity. Construct validity of the scale has been demonstrated by the scale's performance being consistent with theoretical predictions (Mishel, 1981; 1984; Mishel & Braden, 1987; Mishel, et al., 1984).

2. Psychological Adjustment. The level of psychological adjustment was measured by the Negative Affect subscale of Positive Affect and Negative Affect Scale (PANAS). The PANAS (20 items) captures mood states of participants (Watson, et al., 1988). Ten descriptor items reflect positive mood state. Only the descriptor items (10) reflect the negative mood dimensions used in this study. The negative descriptor items are rated on a five point Likert scale and are anchored from "very slightly or not at all" to "extremely". Lower scores indicate less negative mood. The internal consistency of negative mood was .87 when administered to college students (Watson et al., 1988). Construct validity of total PANAS was determined by factor analysis with two factors: positive and negative (Watson, et al., 1988).

3. Enabling Skills. The variable of enabling skills was indexed by Self-Control Schedule (SCS). The SCS (Rosenbaum, 1980), 32-items, has three subscales: problem solving skills (11 items), cognitive reframing (10 items), and belief in self (six items). Problem solving involves the ability to apply problem solving strategies such as planning, problem definition, evaluating alternatives, and anticipation of consequence. Cognitive reframing is the use of cognitions and self-instructions to cope with emotional and physical responses. Belief-in-self is defined as a general belief in one's ability to self-

regulate internal events (Rosenbaum, 1983). Braden (1986) adapted the original SCS into a 100mm visual analog scale. It is designed to be self-administered. Reported internal consistency reliability of the total SCS is .89. The internal consistency of subscales: problem solving, cognitive reframing, and belief-in-self were reported as .71, .65, and .59 respectively (Richards, 1985). Evidence of predictive validity has been reported in the clinical sample (Weisenberger, Wolf, Mittwoch & Mikulincer, 1990). The items are scored in a positive direction for higher level enabling skills; the higher the scores the more enabling skills one has.

4. Self-Help. The variable of self-help was indexed by the Inventory of Adult Role Behavior (IARB). The IARB (45 items) was adapted by Braden (1990b) from Given's scale (1984). The IARB measures the degree to which individuals were involved in sex roles, leisure, social activities, family, and self-care. Cronbach alpha was estimated at .90 (Braden, 1990b).

Table 3.5 summarizes the above scales, their reliability, and validity. A copy of each of the above scales can be found in Appendix C.

Table 3.5. Instrumentation for Proximal Outcome Variables.

Variable	Instrument/Measure	# of Item & Format	Reliability	Validity
Uncertainty Management	Mishel Uncertainty in Illness Scale (MUIS)	33 Items VAS	α= .91	Convergent Construct (Mishel, 1990b)
Psychological Adjustment	Positive and Negative Affective Schedule (PANAS)	20 Items 5 point Likert		
	• Negative Affect		α= .87	CFA (Watson, et al., 1988).
Enabling Skills	Self-Control Schedule (SCS)	32 Items VAS	α= .89	Predictive (Weisenberger et al., 1990)
	1. Belief in Self Subscale		α= .59	
	2. Cognitive Reframing Subscale		α= .65	
	3. Problem Solving Subscale		α= .71	
Self-Help	Inventory of Adult Role Behavior (IARB)	45 Items	α= .90	

Distal Outcome Variable: Well Being

Distal outcome is a consequence, a long term effect of the treatment. The distal outcome variable in this study is 'well-being', a latent variable. Thus, the distal outcome of 'well-being' was indexed by two measures: Index of Well-being (IWB) and Cantril Ladder (CL).

Index of Well-Being (IWB). The IWB, nine item semantic differential scale, measures the life quality perceived by participants (Campbell, et al., 1976). The item uses the 100mm visual analog format (Braden, 1986), and is anchored from "boring" to "interesting". Scoring of the IWB is in a positive direction; the higher the scores the greater perception of overall well-being. The construct validity was documented by Campbell et al. (1976).

Cantril Ladder (CL). The CL (three items scale) measures one's perceived life quality at various projected times: currently, six months from present, and five years from present. The item uses a 10 rung format, with the bottom rung being the worst possible and highest being the best possible (Kilpatrick & Cantril, 1960).

Table 3.6 summarizes the scales, the Cronbach Alpha Coefficient, and type of validity for each scale's performance in prior study. A copy of each of the above scales can be found in Appendix C.

Table 3.6. Instrumentation for Distal Outcome Variable.

Variable	Instrument/Measure	# of Item & Format	Reliability	Validity
Well Being	Index of Well-being (IWB)	9 Items VAS	α=*	Construct (Campbell et al., 1976).
	Cantril Ladder (CL)	3 Items Self Anchoring Ladder	α=*	

Note: * = To be Determined in This Study

Data Collection Procedure

In general, the intervals for data collection were similar for all subjects. The actual format (mail versus face to face) and setting (home versus other meeting place) varied across subjects. Flexibility in the data collection procedure was necessary to accommodate subjects' convenience, minimize intrusion, and lessen fatigue for the subjects. There were six data collection points:

T_0 - baseline, before implementation of SHIP intervention;

T_1 - posttest, immediately after the SHIP intervention and between six to eight weeks after baseline;

T_2 - three months after posttest;

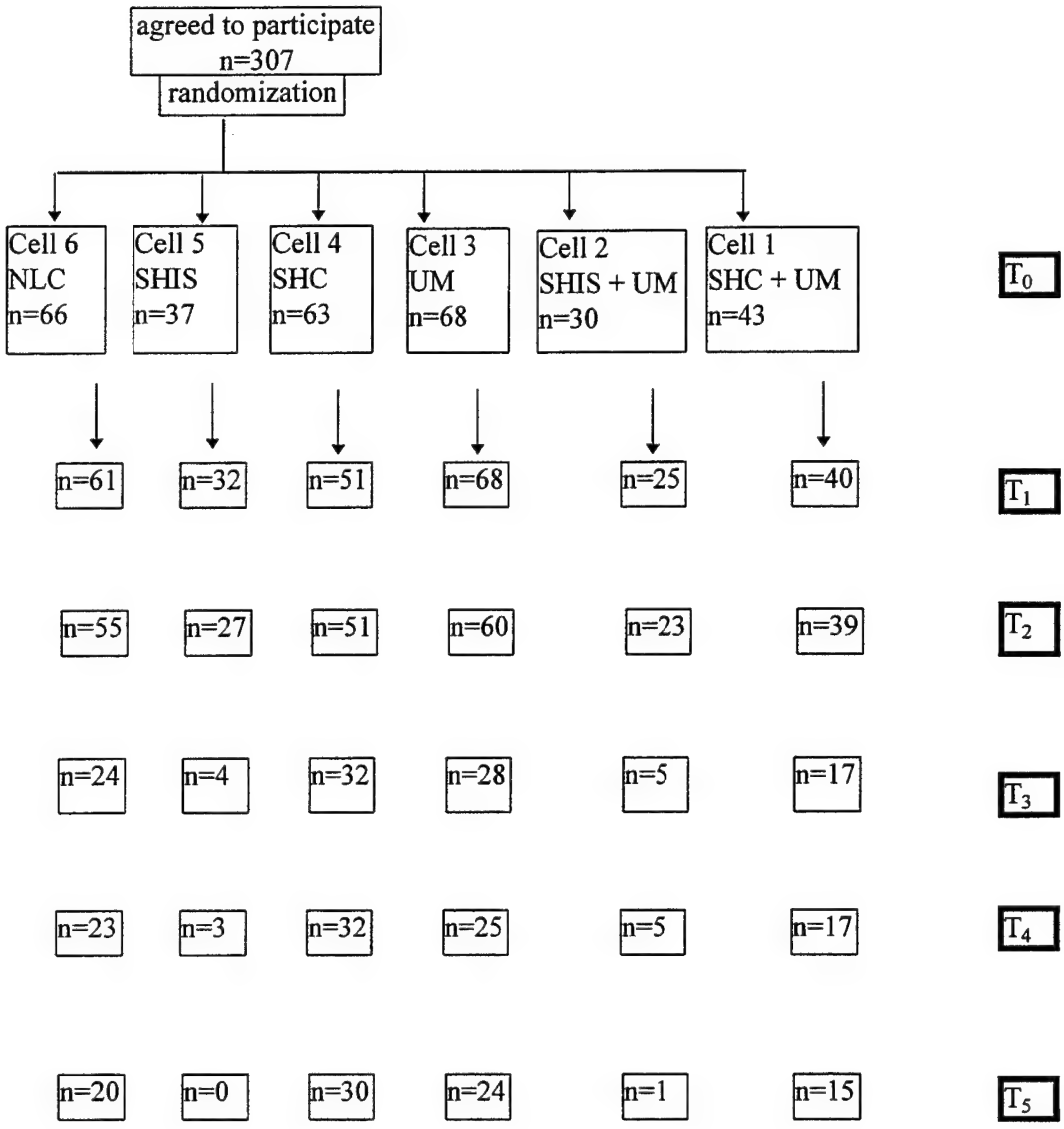
T_3 - six months after posttest;

T_4 - nine months after posttest; and

T_5 - twelve months after posttest.

The data collection period began within six, seven, and 12 weeks for women on medical therapies of radiation, chemo, and hormone respectively, after breast cancer diagnosis. All participants were followed for a period of one and a half years Data collection points and attrition rate are outlined in Figure 3.3.

Figure 3.3. Data Collection Points and Attrition Rate of the Self-Help Intervention Project (SHIP)



Legend:
NLC = Natural Learning Condition
SHIS = Self-Help Independent Study
SHC = Self-Help Class
UM = Uncertainty Management

After the initial contact by phone and agreement to enter the study, the subjects were scheduled for the baseline structured interview, a data collection point (T_0). The structured interview format was used to ensure understanding of the questionnaires and ease respondent burden. For each data collection point thereafter, the subjects were allowed to choose the most convenient method for data collection. Based upon their preference, the data were collected by: 1) completion by the subject at home and mailed in, 2) completion using structured interview format with a trained data collector at a place and time that was convenient for the subject, or 3) for the social support scale data collection, completion by the subject at home required assistance of a data collector by phone., after which the data was mailed in by the subject.

Figure 3.3 shows that attrition rate increased from T2 and after. Among all groups, the attrition rate in the "Self-Help Independent Study-SHIS"-related groups was highest. This high differential attrition rate was, in part, artificially induced by delay-in-funding constraints. When continuation funding arrived, the time frame for T3 data collection had already passed. Secondly, it was discovered that as much as 50% of all subjects assigned to the SHIS-related groups did not perform intervention activities as prescribed by protocol. Meanwhile, subject referrals were not supported by one of the major referral centers. For mentioned reasons, a decision was made by the researchers to discontinue further assignment of subjects to the SHIS-related groups.

In longitudinal studies, a high attrition rate is not unique. In general, attrition rate or missing data points has been handled by: 1) dropping the problem cases from the study; or 2) substituting the missing data point with his/her own mean scores or others' mean scores. Dropping cases from the study associates with costs: dollars and statistical power. Substituting mean scores associates with increased standard error.

In the present study, missing data was handled in several steps. STEP 1: The individual's score on each variable and at each data point was derived by using a weighted mean score. For example, if subject'#1' answered only 29 items out of 30 possible items on variable 'X' at T_0, her score was weighted by 29 for T_0. If subject '#1' answered 30 items out of 30 possible items on variable 'X' at T_1, then her score was weighted by 30 for T_1. This method is advocated in order to minimize missing data at 'variable level' (Figueredo, 1996).

STEP 2: Individual's weighted mean scores on each variable were used in the next step of Individual Growth Curve Analysis (IGCA). IGCA was used to estimate 'intercept' and 'slope' parameters for each variable. For example, subject'#1''s weighted mean scores for variable 'self-help' at T_0 (76.30), T_1 (89.00), T_2 (90.90), T_3 (89.90), T_4 (87.75), T_5 (92.00) were used to estimate subject'#1' intercept (80.27) and slope (2.11) parameters for self-help. Although estimated parameters are more stable with more data points, it is acceptable to estimate parameters with three data points (Figueredo, 1996; McArdle & Epstein, 1987; Meredith & Tisak, 1990). In this study, only those subjects

who attrited and had only two or less data points were dropped from further analysis. That is, any subject who had three or more data points during the study were included in the analysis of change and model testing phase.

STEP 3: A latent factor called 'missingness' was created from degree of missing data points, i.e. 1, 2 and 3 as similar to a technique suggested by Duncan and Duncan (1994). Latent factor of 'missingness' was then used to check for bias that might have been unique with those who had less completed data points than those who had all six data points.

Specific Hypotheses to Be Tested

Derived from the major propositions of this study, the following research hypotheses are conjectured and organized according to the major categories within the evaluative framework (Figure 2.2) proposed in chapter II.

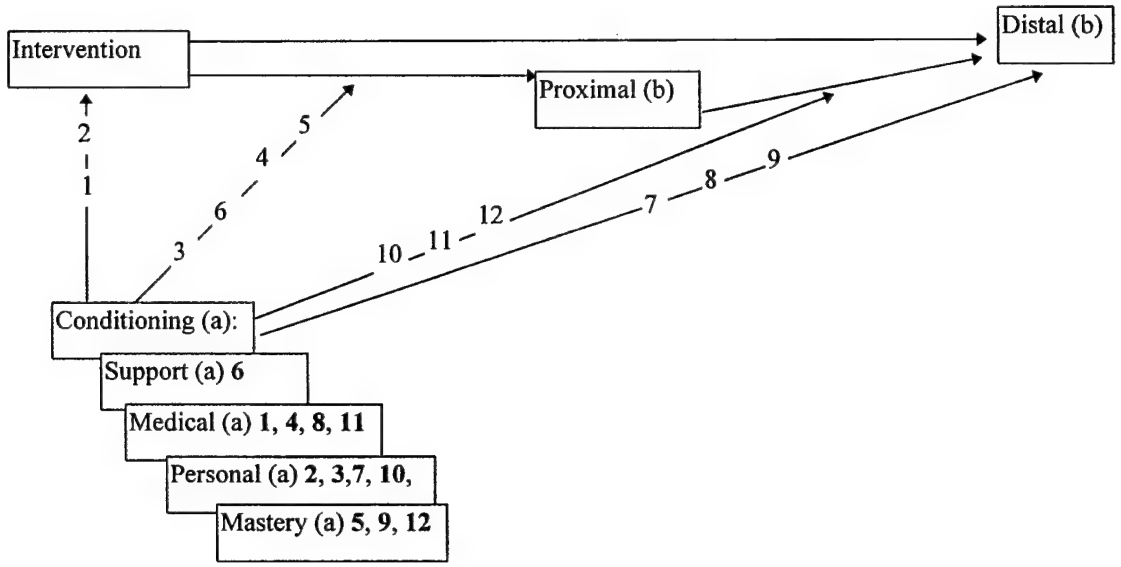
Specific Hypotheses Related to Conditioning Variables.

Conditioning factors refer to characteristics of the patient, her therapy-related status, and her disease-related status. Propositions related to conditioning variables are outlined in Figure 3.4.

1. Conditioning variables influence intervention directly (**i**).
2. Conditioning variables influence proximal outcome indirectly (**j**).
3. Conditioning variables influence distal outcome directly (**l**).
4. Conditioning variables influence distal outcome indirectly (**m**, **k**).

Figure 3.4 Proposed Hypotheses Related to Conditioning Factors to Be Tested

Notes: (a) represents initial level, (b) represents rate of change, 1 to 12 are proposed hypotheses



Accordingly, the specific hypotheses related to PROPOSITION ONE, conditioning variables directly affect intervention (i):

Hypothesis 1. The initial level of personal characteristics, i.e. socio economic status (SES) may affect subjects' participation fully in the SHIP intervention (**1 in Figure 3.4**).

Hypothesis 2. Medical characteristics of therapy and disease-related status may affect subjects' participation fully in the SHIP intervention (**2 in Figure 3.4**).

Accordingly, the specific hypotheses related to PROPOSITION TWO, conditioning variables influence proximal outcomes indirectly (j):

Hypothesis 3. Participants' initial levels (**a**) of personal characteristics moderate the effects of SHIP intervention on proximal outcomes (self-help, enabling skills, uncertainty, psychological adjustment) (**3 in Figure 3.4**). Participants' initial levels of personal characteristics indirectly affect the rate of change (**b**) in self-help, enabling skills, uncertainty, psychological adjustment, and social support over time.

Hypothesis 4. Participants' initial levels (**a**) of therapy-related and disease-related medical characteristics moderate the effect of SHIP interventions on proximal outcomes (self-help, enabling skills, uncertainty, psychological adjustment) (**4 in Figure 3.4**). Participants' initial levels of medical characteristics indirectly affect the rate of change (**b**) in self-help, enabling skills, uncertainty, psychological adjustment, and social support over time.

Hypothesis 5. Participants' initial levels (**a**) of mastery moderate the affect of SHIP interventions on proximal outcomes (**5 in Figure 3.4**). Participants' initial levels of mastery indirectly affect the rate of change (**b**) over time in self-help and enabling skills.

Hypothesis 6. Participants' initial levels (**a**) of social support moderate the effect of SHIP intervention on proximal outcomes (**6 in Figure 3.4**). Participants' initial levels of social support indirectly affect the rate of change (**b**) in social support, uncertainty management, and psychological adjustment.

Accordingly, the specific hypotheses related to PROPOSITION THREE, conditioning variables influence distal outcome directly (l), are:

Hypothesis 7. Participants' personal characteristics directly affect the rate of change (**b**) in 'well-being' (**7 in Figure 3.4**).

Hypothesis 8. Participants' medical characteristics directly affect the rate of change (**b**) in 'well-being' (**8 in Figure 3.4**).

Hypothesis 9 Participants' initial levels (**a**) of mastery directly affect the rate of change (**b**) in 'well-being' (**9 in Figure 3.4**).

Accordingly, the specific hypotheses related to PROPOSITION FOUR, conditioning variables influence distal outcome indirectly (m, k), are:

Hypothesis 10. Participants' initial levels (**a**) of personal characteristics moderate the affect of SHIP interventions on distal outcome (**10 in Figure 3.4**). Participants' initial

levels (**a**) of personal characteristics indirectly affect the rate of change (**b**) in 'well-being'.

Hypothesis 11. Participants' initial levels (**a**) of medical characteristics moderate the effect of SHIP interventions on distal outcome (**11 in Figure 3.4**). Participants' initial levels (**a**) of medical characteristics indirectly affect the rate of change (**b**) in 'well-being'.

Hypothesis 12. Participants' initial levels (**a**) of mastery moderate the effect of SHIP interventions on distal outcome (**12 in Figure 3.4**). Participants' initial levels of mastery indirectly affect the rate of change (**b**) in 'well-being'.

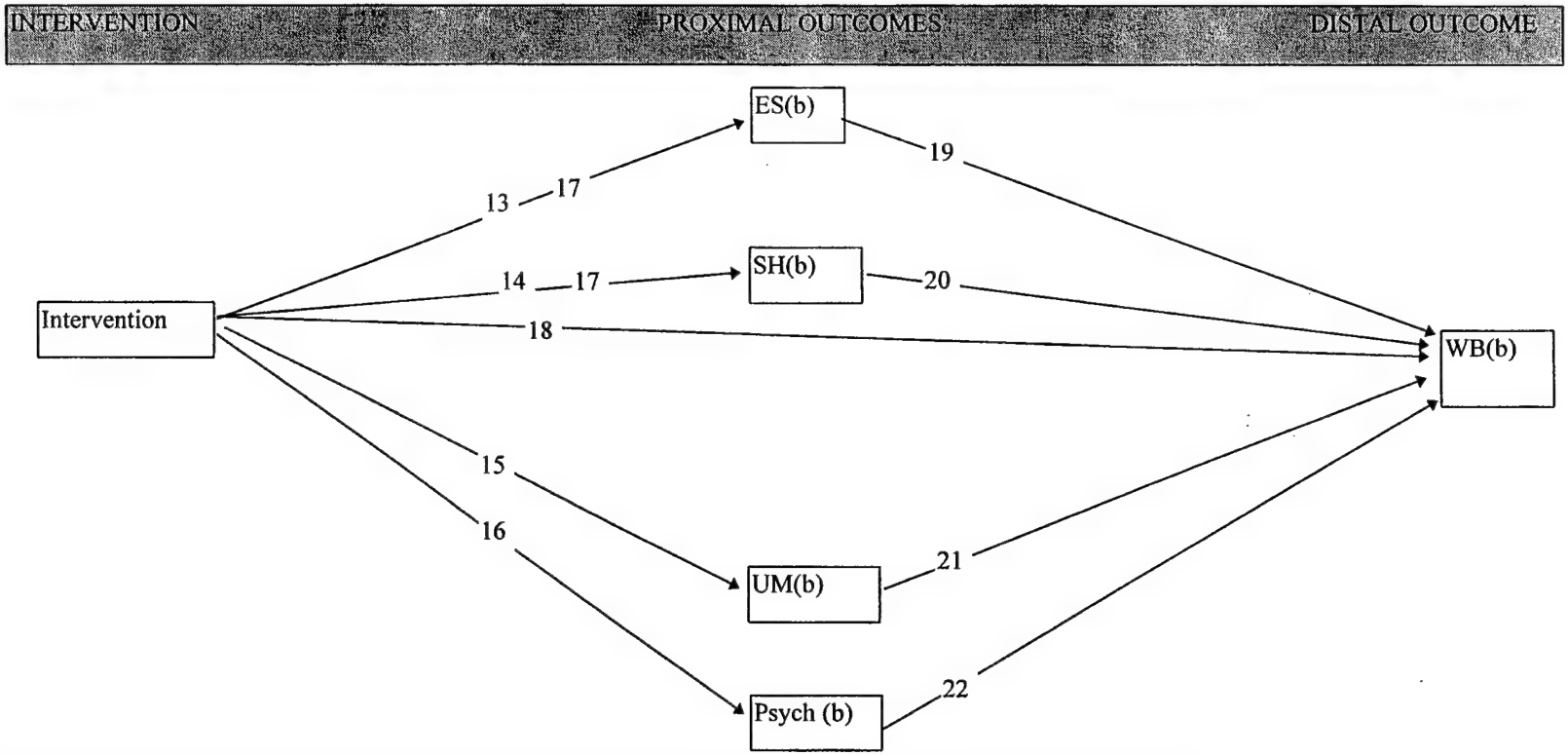
Hypotheses Related to Intervention Variables.

Intervention category refers to the psychoeducational services provided to the women, as compared to conventional care. Propositions related to Intervention category are (Figure 3.5):

1. Intervention variables directly affect (**c**) distal outcome.
2. Intervention variables have indirect effect (**a*b**) on distal outcome. Proximal outcome acts as a mediator between the intervention and the distal outcome.

Consequently, the specific hypotheses related to PROPOSITION FIVE, intervention variables directly affect (c) distal outcome:

Figure 3.5 Proposed Hypotheses Related to Intervention, Proximal, and Distal Outcomes to Be Tested



Notes: (a) represents initial level, (b) represents rate of change, 13 to 24 are proposed hypotheses

Legend:

ES = Enabling Skills
SH = Self-Help
WB = Well Being
UM = Uncertainty Management
Psych = Psychological Adjustment

Hypothesis 13. Those being in either the Self-Help Independent Study (SHIS) or Self-Help Class (SHC) only will experience change (**b**) toward better enabling skills (**13 in Figure 3.5**). Pattern of change is expected to be positive.

Hypothesis 14. Those being in either the Self-Help Independent Study (SHIS) or Self-Help Class (SHC) only will experience change (**b**) toward more self-help (**14 in Figure 3.5**). Pattern of change is expected to be positive.

Hypothesis 15. Those being in Uncertainty Management (UM) only will experience change (**b**) toward less uncertainty over time (**15 in Figure 3.5**). Pattern of change is expected to be negative.

Hypothesis 16. Those being in Uncertainty Management (UM) only will experience change (**b**) toward better psychological adjustment or less negative affect over time (**16 in Figure 3.5**). Pattern of change is expected to be negative.

Hypothesis 17. Those being in the combined interventions of UM and SHIS or UM and SHC, will experience over time a change (**b**) toward less negative affect (negative change pattern), less uncertainty (negative pattern of change), more self-help (positive change pattern), and better enabling skills (positive change pattern) (**13 to 16 in Figure 3.5**).

Consequently, the specific hypotheses related to PROPOSITION SIX, intervention variables directly affect (c) distal outcome:

Hypothesis 18. Those participants being in any SHIP intervention component will experience change (**b**) toward better 'well-being' (**18 in Figure 3.5**). Pattern of change is expected to be positive.

Hypotheses Related to Proximal Outcome Variables.

The proximal outcomes are related to change in the clients as a direct consequence of the services provided. The distal outcome is related to the change in the clients as an indirect consequence of the services provided. The proposition related to proximal outcomes is (Figure 3.5):

1. Proximal outcome variables directly affect (**b**) the distal outcome variable.

Hence, the specific hypotheses related to PROPOSITION SEVEN, proximal outcome variables directly affect (b) the distal outcome:

Hypothesis 19. A change over time (**b**) in enabling skills will lead to a change (**b**) in well-being over time (**19 in Figure 3.5**).

Hypothesis 20. A change over time (**b**) in self-help will lead to a change (**b**) in well-being over time (**20 in Figure 3.5**).

Hypothesis 21. A change over time (**b**) in level of uncertainty will lead to a change (**b**) in well-being over time (**21 in Figure 3.5**).

Hypothesis 22. A change over time (**b**) in psychological adjustment will lead to a change (**b**) in well-being over time (**22 in Figure 3.5**).

Data Analysis Plan

The emphasis of this study is on individual differences in change, and growth or decline over time. Subjects who participated in SHIP interventions are expected to have fluctuated up or down on specified outcomes; it is the amount of fluctuation that is the focus of the study. The process is partly facilitated by the longitudinal model available in the SHIP study. The longitudinal model enables 1) assessment of individual variation; and 2) relating individual variation to conditioning factors (Muthen, 1996; Muthen & Curran, in press).

Traditionally, the efficacy of an intervention program has been assessed by using time-specific comparisons of mean scores between treatment groups and control group. True random assignment to groups attempts to equate the treatment and control groups prior to implementation of an intervention (Cook & Campbell, 1979); treatment effect then is typically measured as the difference between the mean values of groups on the outcome at the end of an intervention trial.

Common traditional analytic techniques include ANOVA, ANCOVA, MANOVA, MACOVA, and multiple regression. Despite their usefulness, these techniques are limited in assessing individual differences, and change over time. Limitations include decreased statistical power, inability to model individual differences in change, unnecessary restriction of inferences that can be gathered from observed data (Muthen & Curran, in press; Rogosa, 1988; Rogosa & Willett, 1985), ineffectiveness in

handling missing data, and not sensitive in dealing with unbalanced designs (Raudenbush, 1995; Ware, 1985) as in the SHIP project.

The main goal of health-related treatment is to alter the natural or normative growth trajectory in dealing with illness. For example, SHIP interventions are designed to accelerate individuals' growth in self-help, enabling skills, and managing uncertainty, thus adjustment to illness, and ultimately improved well-being. Therefore, the efficacy and effectiveness of SHIP interventions is the degree to which the interventions can alter the normative growth that exists without exposure to SHIP interventions. It is important that new analytic methods be used to address the complex issue of individual as well as longitudinal growth so that stronger and more informed inferences can be made about the efficacy of an interventions program such as SHIP.

Growth curve modeling (GCM) has been advocated as the most sensitive strategy in assessing individual differences (Duncan & Duncan, 1994; McArdle & Epstein, 1987; Meredith & Tisak, 1990; Muthen, 1996; Muthen & Curran, in press; Rogosa, 1988; Rogosa & Willett, 1985). GCM provides a more comprehensive understanding of the treatment and control group growth process over time. It is known that not all treatment works for all people (Kellam et al., 1991). It is therefore important to identify those subjects who are most benefited from SHIP interventions. The GCM allows for estimation of individual differences in change over time. This differential response is

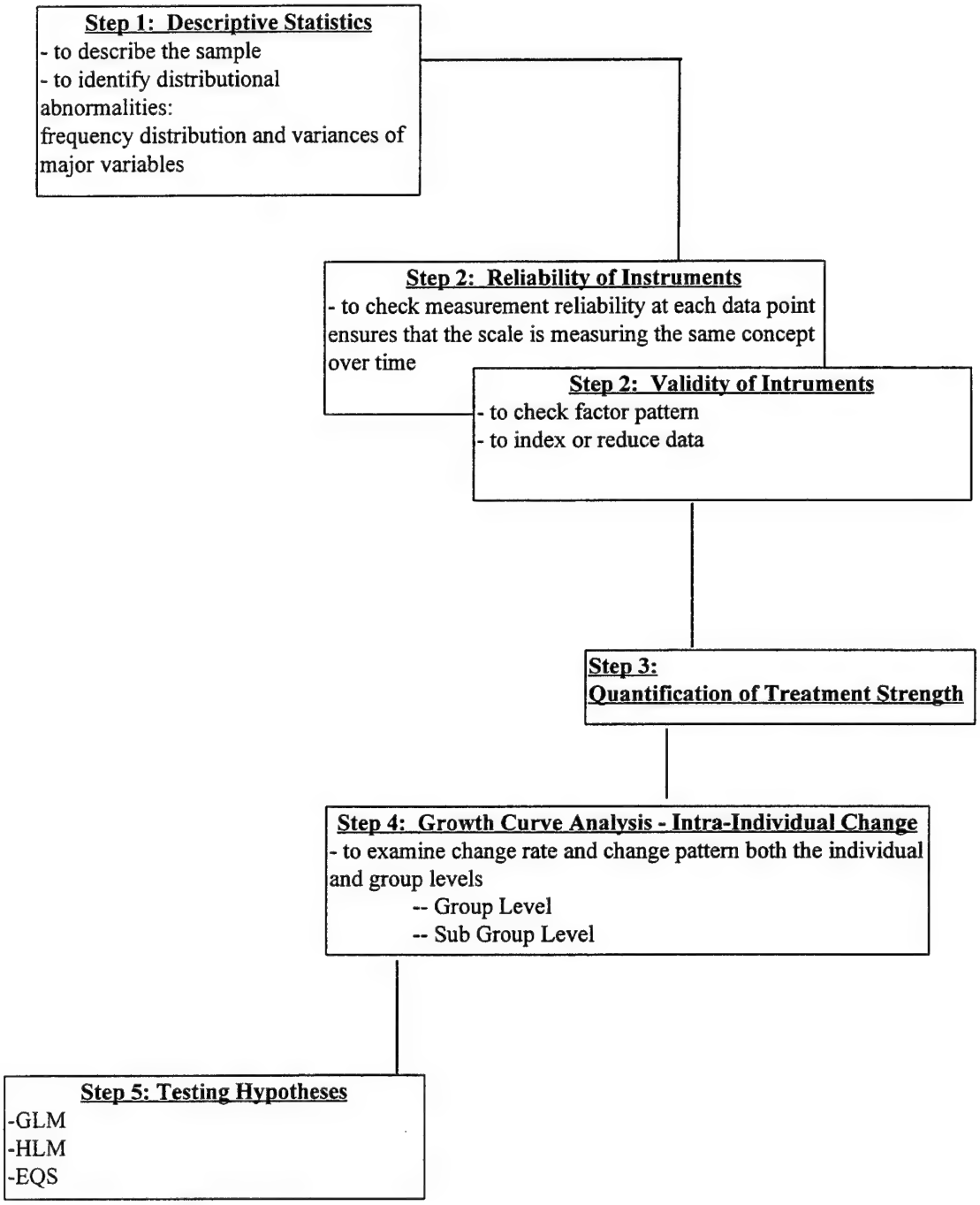
useful in identifying which factors are associated with stronger or weaker responses to SHIP interventions.

In this study, factors associated with differential responses to be examined are categorized: personal, medical, social support, and mastery at initial level prior to entering into SHIP interventions. The efficacy of the SHIP interventions on the distal outcome is examined while accounting for the moderation effects of the conditioning variables and the mediating effects of the proximal outcome variables. The interventions are expected: 1) to indirectly affect the change in distal outcome of perceived well-being, and 2) these indirect effects are conditional based upon the conditioning variables. The hypotheses reflect the individual differences in response to psychoeducational interventions, as well as the complexities of reality. Consequently, multiple levels of statistical analyses, including use of growth curve modeling and structural equation modeling, empirically examine the proposed hypotheses. The statistical tests are conducted in steps; each step provides necessary information to perform the analysis in the next step (Figure 3.6).

Step 1: Descriptive Statistics

In the initial stage, descriptive statistics are used to describe the sample of demographic characteristics, as well as major variables at all data points. The frequency distribution and variances of major variables are examined to identify distributional

Figure 3.6 Data Analysis Plan



abnormalities, if any, that preclude the use of particular statistical tests. The Statistical Package of Social Sciences-Personal Computer (SPSS-PC) version, SAS version six by SAS Institute Inc., Statistica (1986) by StatSoft, Inc., and Equation Structural Modeling (EQS) by Peter Bentler (1992) are the primary statistical packages used for data analyses in this study.

Step 2: Assessment of Instruments: Reliability and Validity

The internal consistency and reliability of instruments measuring the variables of interest in this study are assessed using the Cronbach alpha coefficient plus factor analysis at each data point. The reliability of instruments was evaluated to determine the source and extent of measurement error, if any; consequently permitting measures to minimize error (error attenuates correlations between variables). Checking measurement reliability at each data point ensures that the scale is measuring the same concept over time (Rogosa, Brandt & Zimowski, 1982). In addition, factor patterns are evaluated for consistency.

Next, each measurement of the variables of interest was evaluated for consistency of factor pattern by using factor analysis. Factor analysis summarizes the interrelationships among the items within each measurement concisely (Gorsuch, 1983). It is a method of data reduction or indexing variables by using factor scores. Factor scores are considered more reliable than the conventional technique of summing scores (Sidani & Jones, 1994; 1996).

Step 3: Quantification of Treatment Strength

In this step, all five components of the SHIP were quantified for strength. At the global level, five experts were asked to rate SHIP treatment strengths according to indicators: **frequency, purity, duration, specificity, intensity,** and **potency**. Of all six indicators, only two indicators were varied across subjects, and were thus appropriate for quantification of potency and intensity. The same experts were asked to rate potency's contribution to outcome. Intensity was assessed as being a proportion of completed lessons. Another dimension of treatment strength was Level of Helpfulness of lessons to the subjects. Together, these indicators/dimensions were indexed to represent the strength of the treatment the subjects received.

Step 4: Growth Curve Analysis - Change Pattern and Change Rate

In this step, change pattern was examined at both the individual and group levels (Bryk & Raudenbush, 1987).

At the individual level, standardized mean scores were used to examine change patterns (variation in slopes) and change rate (steepness of slopes) using individual growth curve analysis (McArdle & Epstein, 1987; Meredith & Tisak, 1990; Muthen, 1996; Muthen & Curran, in press).

Change Pattern at Within Individual Level (First Level Change): The level and pattern of change on each outcome variable can be captured by using individual growth curve analysis (Raudenbush & Chan, 1992; Nesselroade, 1991). Change is the trajectory

that represents the relationship between variables of interest versus time. That is, the value of the variable of interest is a function of time. This functional relationship can be straight (linear) or non-straight (curvilinear) and is represented as:

$$Y_{it} = B_{0i} + B_{1i}X_{it} + R_{it}$$

where:

$\mathbf{B_{0i}}$ is the intercept and describes the initial status or average level of Y for an individual when the variable of time equals zero;

$\mathbf{B_{1i}}$ is the slope and describe the direction as well as rate of change in Y at an individual level;

$\mathbf{X_{it}}$ represents the time variable or measurement occasions i.e. T_1, T_2, T_3, etc.

$\mathbf{R_{it}}$ is considered as "random error" in Y for each individual at each measurement occasion. Besides measurement error, there is the prediction error which is the individual's score (observed score) which deviates from the prediction line. Both measurement error and prediction error are combined within the "random error" term.

Change Pattern at Between Individuals Level (Second Level Change): This level of change is examined by mixed model analysis of variance. Separate analysis is conducted for each outcome variable and for each treatment group in order to examine change patterns over time. This step is necessary for profiling patterns (improving, no change, or worsen) within a group prior to comparing across groups.

Step 5: Hierarchical Linear Model (HLM)

After checking for intra-individual change, differences between individuals of intercepts and slopes are examined. Intercept and slope parameters among five treatment groups are compared using the general linear model (GLM). The GLM was selected because of its flexibility to types of data, i.e. categorical or continuous. A change in slope indicates treatment effect.

Using the hierarchical linear model (HLM), slopes of all variables of interest were hierarchically regressed onto independent variables of the treatment. In the preceding step, the contribution of each variable and the explanatory power of the model can be clarified (Francis, Fletcher, Stuebing, Davidson & Thompson, 1991; Bryk & Raudenbush, 1987; Rogosa, 1991).

In this study, a model explaining the individual's slope for each proximal and distal outcome was specified in order to test the specific hypotheses proposed above. For testing purposes, an equation is specified for each proposed hypothesis. Thus, all direct affects, as well as moderating affects, are tested. For example, moderating affects of medical characteristics on the proximal outcome of enabling skills and on the distal outcome of well-being were tested separately. An interactive term between the medical characteristics and the treatment represents the moderating effect.

Limitations of the Study

Despite the solid design and fastidious implementation of the SHIP interventions, this study is limited to the collected data. Secondary data analysis imposes limitations: inability to modify the study design such as gaining more data points, and inability to change the operationalization of concepts such as use of alternate measurement methods.

Attrition is a major factor in any longitudinal study, including the SHIP interventions. Efforts were made to retain subjects for the duration of the study period. Attrition was a problem at T_3, thus small sample size reduces the statistical power of the study. Differentiation in sample size existed in the SHIP study. The sample size was adequate during the treatment phase (T_0 to T_2) , but sharply dropped during the follow-up phase (T_3 to T_5). As discussed earlier, not all subjects got a chance to continue participation during the follow-up phase. Subjects attrited due to lack of timely funding, not due to other processes such as self-selection. Thus, the alpha level was set at .10 to determine statistically significant effects. A higher alpha level was set in order to reduce the risk of making a Type II error; that is, accepting a false null hypothesis that there was no significant difference between groups, while in fact there was a significant difference (Munro, Visintainer & Page, 1986).

Self-reports have inherent methodological limitations, including reliance on memories, especially in repeated measures using the same instrument. In this study, memories may be weak due to the time intervals of two months or more between measurements.

Selection bias refers to volunteerism in the study. Self-selection motivated by wanting to learn, having free time, or feeling well can limit the generalizability of the results of this study to the sample group itself. It is not possible to infer that the results of the sample apply to the larger target population of women being treated medically for breast cancer.

Summary

Data gathered from the primary project (SHIP: an experimental, repeated measures study) were analyzed in this secondary data analysis to test for efficacy based on the proposed evaluative framework. Change in pattern and rate were examined both at individual and group level.

In this chapter, a discussion of the study's research design, criteria for inclusion, human subjects' protection, the sample, and the setting were discussed. Next was the discussion of the instrumentation, including measurements for: 1) the conditioning variables, 2) the treatment variables (independent variables), 3) the proximal outcome variables, and 4) the distal outcome variable. Followed by the discussion of data collection procedures, specific hypotheses to be tested by this study, and the data analysis plan were presented.

CHAPTER IV

RESULTS

The results of the data analyses are presented in this chapter. Description of results are detailed in order to discriminate patterns of change, even when results fail to demonstrate a significant statistical difference between SHIP treatment groups and the natural learning condition group.

The primary purpose of this study was to further develop treatment theory for SHIP interventions. The first objective of this study was to determine which of the five interventions resulted in significant improvement of patients' perceptions regarding 'well-being'. The second objective of this study was to assess the stability of SHIP's treatment effects during an extended 12 month follow-up data collection period.

Specifically, the present study attempted to: 1) determine which SHIP interventions and activities were most beneficial in promoting perceived 'well-being' in women receiving adjuvant therapy for breast cancer; 2) profile which individuals were most likely to benefit from specific SHIP interventions, and 3) test the processes by which SHIP interventions affected the outcomes.

In order to meet the above mentioned objectives, results of data analyses are organized in numerous sections. The study samples are first described in detail, necessary steps to prepare the data for further analyses are explicated, reliability of instruments used in this study are examined, quantification of SHIP treatment strengths

are presented, examination of change rate and pattern as related to treatment efficacy of SHIP interventions are delineated, and finally evaluation of the 22 proposed hypotheses is offered.

Description Of The Sample

Several criteria for inclusion were imposed in selection of the subjects. The criteria were: 18 years of age or older; able to read and write English; and concurrently receiving adjuvant therapy for either primary or recurrent breast cancer. The sample was representative of "typical" patients who were seeking care for breast cancer. Any woman who met the above criteria and entered any one of the referral sites was eligible for inclusion in the SHIP study. Patients had a choice of whether or not to participate in the study; thus nonprobability sampling was used to identify the 307 women who participated in the SHIP study.

In this section, the subjects' personal characteristics, medical characteristics, initial mastery level, and initial level of social support are described. These characteristics are factors that can potentially moderate the effects of the independent variable/treatment upon the specified outcomes (Chen & Rossi, 1987; Costner, 1989; Finney & Moos, 1989); as well as enhance or obscure the actual benefits/effects of the interventions.

Personal Characteristics

The characteristics of women in this study were consistent with the reported literature on demographics of women who were being treated for breast cancer. Ages ranged from 25 to 82 years. Most subjects were married (63%). Most women were either employed full-time (23.1%), or retired (27.2%). Eighty-seven percent of the sample was white American. The educational level was high, with the majority of the subjects having at least some college (30.7%). A third of the sample (32.1%) lived in a household with a family monthly income of approximately $1,500.

A summary profile presents the "typical" patient in this study as being white female in middle age (55.5 years, ± 12), married, employed full-time or full-time student or retired, with at least some college education, and a family income of approximately $1,500 per month.

Baseline comparisons between six treatment groups (Self-Help Class, Self-Help Independent Study, Uncertainty Management, Natural Learning Condition, and two combination groups) using one-way analysis of variance (ANOVA) and the Chi-square test revealed no statistically significant differences in age, marital status, employment status, race, educational level, or income. Thus, personal characteristics were equivalent among all specified groups in the study prior to the SHIP interventions.

Medical Characteristics

Medical characteristics represent disease-related factors and therapy-related factors specific to the patient. Medical characteristics represent illness/wellness of patients.

Disease-related factors include cancer staging, presence of metastasis, and co-morbidity. Cancer staging refers to the extent of breast cancer found at time of diagnosis. Metastasis represents breast cancer as evidenced outside breast tissue at time of diagnosis. Co-morbidity refers to the number of other chronic illnesses that patients are experiencing concurrently. Nearly half (44%) of the study's subjects were at stage I of breast cancer, and roughly 83% of the study's sample had experienced breast cancer for the first time. Eighty percent (80%) of the subjects had experienced no metastasis of cancer outside the breast site. More than half (52%) of all subjects had no other chronic illness, while the remaining majority group (33%) had one other chronic illness.

Therapy-related factors include primary therapy and adjuvant therapy. Primary and adjuvant therapies are medical therapies such as surgeries, chemotherapy, radiation therapy, hormone therapy, or hyperthermia therapy. The most common types of primary therapy experienced by the subjects of the study were lumpectomy (38.4%) and modified radical mastectomy (37.1%). The most common type of adjuvant therapy was radiation (2.2%). An equal number of patients received chemotherapy (1.3%) and hormone therapy (1.3%).

Medically, the 'typical' subject experienced, on average, less than one other chronic illness besides breast cancer. Related to breast cancer status, the typical subject at diagnoses experienced primary breast cancer rather than a recurrent or metastatic cancer. Consequently, she experienced typically stage I breast cancer. Moreover, the 'typical'. subject gave baseline data 110 days after having been diagnosed with breast cancer, and she typically participated in SHIP interventions nine days after providing the baseline data.

Baseline comparisons among six treatment groups (Self-Help Class, Self-Help Independent Study, Uncertainty Management, Natural Learning Condition, and two combination groups), using both the one-way analysis of variance (ANOVA) and the Chi-square test, revealed no statistically significant differences in number of other chronic illnesses, metastasis, stage of breast cancer, medical therapy for breast cancer, or number of days after diagnosis to inclusion in the SHIP interventions. Thus, medical characteristics were equivalent among all groups prior to SHIP interventions.

Support Characteristics

Support characteristics consist of levels of social support and levels of mastery. Social support refers to the need (size, use, and satisfaction) of support available to patients (Barrera, 1980), as well as the subjects' perceived functioning level with her significant others (Spanier, 1988). Social support level was measured via the Arizona Social Support Interview Schedule (ASSIS) (Barrera, 1980). Mastery is defined as the

level of belief-in-self as being capable of influencing one's behavior, and overcoming adversities (Pearlin & Schooler, 1978). Mastery level was measured with the Mastery Scale (MS) (Pearlin & Schooler, 1978).

Fifty percent of the subjects scored moderate, and a tenth (12%) scored low on the ASSIS scale, meaning most women perceived themselves as having available moderately tangible and moderately intangible support from others. At baseline, half of the subjects scored high (51%), and a third scored moderate (34%) on the Mastery Scale, meaning women had a moderate to high belief-in-self as being capable of influencing the situation, as well as being capable of overcoming obstacles. "Typical" information was captured as the mean score, and is reported at Table 4.1.

Baseline comparisons between six treatment groups (Self-Help Class, Self-Help Independent Study, Uncertainty Management, Natural Learning Condition, and two combination groups), using one-way analysis of variance (ANOVA) and the Chi-square test, revealed no statistically significant difference in perceived level of support versus mastery (Table 4.1). Thus, support and mastery characteristics were equal among all groups prior to SHIP interventions.

Preparation Of Data

In this section, specific steps were taken: 1) to assess the measurements used in this study; and 2) to examine missing data. Each step is described and presented with findings.

Table 4.1 Support Characteristics of the Typical Patient

Support Characteristics	S.D.	Sample Mean	Cell1 Mean SHS/UM	Cell2 Mean SHIS/UM	Cell3 Mean UM	Cell4 Mean SHC	Cell5 Mean SHIS	Cell 6 Mean NLC
Support Level	9.38	38.07	36.18	42.24	39.56	37.65	37.86	35.15
Mastery Level	20.64	70.91	67.81	72.65	72.16	73.37	65.39	72.14

Notes:
S.D. = Standard Deviation of Sample Mean
NLC = Natural Learning Condition
SHIS = Self-Help Independent Study
SHC = Self-Help Class
UM = Uncertainty Management

Assessment Of Instruments

The first step was to assess psychometric properties of instruments used in measuring the variables of interest by using the Cronbach alpha coefficient at each data point. Internal consistency of instruments was estimated in order to determine the extent of measurement error. Measurements with higher measurement error can lower correlation scores between variables.

Overall, measures were internally consistent with a Cronbach alpha higher than .70; most were above .80. The only exception was the Cantril Ladder. The Cantril Ladder performed somewhat unstably with Cronbach alphas ranging from .46 (T_0) to .71(T_3 and T_4). The Cantril Ladder was used for single item indicators of life quality at present, in the short term future (6 months), and in the long term future (5 years). Reliability of measures in the form of standardized item alpha coefficients for the six data points are reported at Table 4.2.

The 'Enabling Skills' scale consists of three subscales: belief-in-self, problem solving, and cognitive reframing, all of which were the focus of the Self-Help Class (SHC) and the Self-Help Independent Study (SHIS)of the SHIP. Using the subscales enabled understanding of the more specific intrapersonal mechanisms by which SHIP interventions worked to bring about changes in outcomes.

The second step related to the assessment of instrument psychometrics was the examination of factor patterns through the use of factor analysis. Measurements were

Table 4.2 Assessment of Measures: Reliability - Standardized Item Alpha for Measures Over All Data Points

Measurements	Baseline T_0	Post-Treatment T_1	3mos Follow-up T_2	6mos Follow-up T_3	9mos Follow-up T_4	12mos Follow-up T_5
Mastery Scale (MS),7 items, Reported $\alpha = .73$	.82 n=303	.81 n=269	.88 n=244	.86 n=104	.89 n=85	.89 n=56
Arizona Social Support Interview Schedule (ASSIS), 42 items, Reported test-retest= . 80	.83 n=217	.84 n=235	.83 n=238	.82 n=100	.87 n=81	.86 n=57
Inventory of Adult Role Behavior (IARB), 20 items, Reported $\alpha = .90$	.92 n=219	.93 n=196	.95 n=207	.95 n=92	.94 n=75	.95 n=50
Mishel's Uncertainty in Illness Scale (MUIS), 33 items, Reported $\alpha = .91$	.92 n=251	.93 n=222	.94 n=210	.94 n=89	.95 n=68	.96 n=43
Negative Affect Scale (PANAS), 10 items, Reported $\alpha = .87$	.88 n=213	.87 n=235	.90 n=232	.90 n=91	.86 n=69	.87 n=28

Table 4.2 (cont') Assessment of Measures: Reliability - Standardized Item Alpha for Measures Over All Data Points

Measurements	Baseline T_0	Post-Treatment T_1	3mos Follow-up T_2	6mos Follow-up T_3	9mos Follow-up T_4	12mos Follow-up T_5
Self-Control Schedule (SCS), 36 items Reported α = . 89	.84 n=259	.87 n=241	.89 n=228	.86 n=97	.87 n=78	.90 n=53
SCS Subscale: Belief-in-Self, 6 items Reported α .59	.73	.73	.70	.66	.76	.77
SCS Subscale: Cognitive Reframing, 10 items Reported α .65	.78	.79	.84	.81	.83	.88
SCS Subscale: Problem Solving, 11 items Reported α .71	.73	.78	.83	.77	.80	.89
Index of Well-Being (IWB),9 item	.91 n=303	.94 n=269	.96 n=246	.95 n=104	.95 n=84	.98 n=56
Cantril Ladder (CL) 3 items	.46 n=195	.57 n=215	.61 n=223	.71 n=95	.71 n=74	.59 n=55

factor analyzed with the following criteria: 1) extraction of all factors with Eigen value greater than one (1.0); and 2) rotation obliquely (OBLIMIN). For the most part, each measure represented one factor (by Scree test) as proposed, and was consistent with prior studies. An exception was the Cantril Ladder. Each item in the Cantril Ladder represented a factor; thus there were three factors in the Cantril Ladder. When the Cantril Ladder was factor analyzed with an Index of 'well-being', the one factor solution was not satisfied. Therefore, in this present study, 'well-being' was indexed with nine items from the Index of Well-Being Scale.

Results of exploratory factor analysis mentioned above aided in the decision regarding how to represent each variable of interest. Conventional techniques for aggregating items within a measure, including summing, has been criticized (Figueredo, 1996; Fisher, 1993; Uphold & Strickland, 1989). The summing/aggregating approach (adding raw scores) assumes that every item within a scale is equal. After examining the factor pattern of each measure, the advantages and disadvantages of using the factor score as a representative score for each variable were weighed. Although the factor score summarizes concisely the interrelationships of the items within each measurement (Gorsuch, 1983), and although the factor score is more reliable than conventional techniques of summing/aggregating scores (Sidani & Jones, 1994; 1996), factor score also reduces variance. Variance is key in examining individual differences, thus a weighted mean score method was used in this SHIP study, instead of the factor score. A

weighted mean score was obtained for each variable at each data point. These weighted mean scores were used in the next step of obtaining the growth curve for each individual (Appendix E). In order to improve the stability of parameter estimations, only those individuals who had a minimum of three data points were included in the individual growth curve analysis of the SHIP study (Muthen & Curran, in press; Rogosa, 1988; Rogosa & Willett, 1985).

Examination Of Missing Data

Attrition of subjects or missing individual data points from the study is a situation not unique in longitudinal studies such as this present SHIP study. Traditionally, attrition or missing data points are handled by: 1) dropping the cases from the study; or 2) substituting the missing data point with the subject's own mean score or others' mean score. Dropping cases from a study associates with costs: dollars versus statistical power. Even if missing data is randomly distributed, substituting mean scores associates with an increase in standard error of estimation (Cordes, 1993; Duncan & Duncan, 1994; Roth & Switzer, 1995).

In the present study, missing data due to attrition were checked for bias. Did the participants attrit due to spontaneous recovery or death, or some other random reason such as relocation or vacation? In this study, the missing data points issue was considered in two steps: estimating individual's score for missing data point(s), and assessing bias related to attrition. Estimation of individual changes over time was

captured by Individual Growth Curve Analysis (IGCA), a strategy which has been endorsed as being more robust to missing data points than traditional techniques (Muthen & Curran, in press; Rogosa, 1988; and Rogosa & Willett, 1985). Individual Growth Curve Analysis (IGCA) can, for example, model individual X's score of variable A at time #4 based on individual X's responses on the same variable at time #1, time #2, and time #3.

Albeit, IGCA is robust in handling missing data, unbalanced design, and unequal spacing of time points across subjects, sources of attrition and imbalance of subjects per treatment group still need to be investigated to insure that these situations do not give rise to erroneous inferences (Rogosa, 1995). This next test of assessing bias related to attrition was done through latent modeling as described by Duncan and Duncan (1994) and others (McKnight, 1996; and Sechrest, 1996). A latent factor representing missing data is created, then in turn is used to model estimated outcomes. No bias (random missing data) is expected if a "missing" factor is not a significant predictor of outcomes. Table 4.3 shows that "missing" factors did not have statistically significant effects in any outcome variables of this SHIP study.

Table 4.3 'Missing' Factor as a Predictor of Outcomes.

Outcomes:	Beta Level	p Level
Belief-in-Self	-.02	.81
Cognitive Reframing	-.05	.46
Problem Solving	-.00	.99
Self-Help	.10	.19
Uncertainty	.12	.11
Psychological Adjustment	-.06	.42
Well-Being	.11	.13

Quantification Of Ship Treatment Strength

The total sample of this study was 307 women who were receiving adjuvant medical therapy for breast cancer. Subjects were randomly assigned to one of the five treatment groups or to the natural learning condition group (control group) (Table 4.4). A roughly equal number of subjects was randomly assigned to the Uncertainty Management Group (Group 3, 22.14%), Self-Help Class group (Group 4, 20.5%), and Natural Learning Condition Group (Group 6, 24.5%). The smaller percentage of the sample was assigned to the remaining categories: the combined categories of Self-Help Independent Study and Uncertainty Management (Group 2, 9.8%); the combined group of Self-Help Class and Uncertainty Management (Group 1, 14%); and Self-Help Independent Study Group (Group 5, 12.05%).

Table 4.4 Sample Distribution in SHIP Intervention Groups.

	Self-Help Independent Study	Self-Help Class	Uncertainty Management
Nurse Case Manager	Group 2 (n=30) 9.77%	Group 1 (n=43) 14%	Group 3(n=68) 22.14%
Naturally Occurring	Group 5 (n=37) 12.05%	Group 4 (n=63) 20.5%	Group 6 (n=66) 24.5%

If the ultimate goal is to have an effective and efficient treatment, then treatment strength should be central in assessing any program/intervention. If delivered as intended and designed, SHIP interventions should affect a change in Proximal Outcomes and Distal Outcome. Treatment strengths of the SHIP interventions in this present study were evaluated according to dimensions put forth by Sechrest and Yeaton (1981). Dimensions include: **specificity, purity, duration, frequency, intensity, and potency,** and were discussed in more detail within previous chapters (Table 3.3). Treatment that delivers six weekly (**frequency**) sessions according to protocol (**purity**) over a six week (**duration**) period is expected to be stronger than the same treatment delivered over a 12 week period. The strength of a treatment is enhanced if there is a clear and detailed protocol specifying (**specificity**) the conditions under which the interventions were intended to be delivered. **Intensity** refers to the proportion of treatment that patients actually received. The strength of a treatment is more potent if, for example, the teacher of the Self-Help Class has a masters degree versus a bachelors degree, and is trained for the job versus not trained (**potency**).

It is possible that subjects' actually received treatment that was different from the intended treatment. Varied dosages of treatment can be due to 1) varied preparation or education level of the various interveners, or 2) varied number of classes which participants attended. A panel of experts (n=5), whose background was in oncology, interventions research, and program evaluation was asked to rank the treatment strength according to the criteria spelled out by Sechrest and Yeaton (1981). Overall, the purity indicator was given the most weight in bringing about positive outcomes from a psychoeducational intervention (80% agreement). The intensity indicator was ranked as the second most important contributor (100% agreement). The potency indicator was ranked last in importance as a contributor (80% agreement). Consequently, varied indicators (intensity and potency) were weighted in the quantification of treatment strength for each subject.

The process of weighting treatment strength is similar to the process of standardization; thus, treatment strength is expressed in the same unit, regardless of the scaling methods involved. Treatment strength is defined in this study as the proportion of the intervention the subjects actually received. Table 4.5 shows that all treatment groups received approximately 47.5% (± 3.5%) of the intended treatments.

Table 4.5 Overall Treatment Strength for Each Treatment Group

	Group 1 SHC/UM	Group 2 SHIS/UM	Group 3 UM	Group 4 SHC	Group 5 SHIS
Mean	44.01%	50.85%	45.23%	53.95%	45.75%
Minimum	15.65%	19.76%	3.57%	7.43%	9.46%
Maximum	82.26%	97.48%	100.00%	87.84%	79.7%
Std Dev	16.97%	20.14%	24.05%	22.38 %	21.14%

Notes: SHC = Self-Help Class Group
SHIS = Self-Help Independent Study
UM = Uncertainty Management

In the following sections are the discussions of how treatment strengths were derived, as well as reports of findings related to treatment strength for each SHIP treatment intervention: Self-Help Independent Study (SHIS), Self-Help Class (SHC), Uncertainty Management (UM), and two combined components (SHIS/UM and SHC/UM). Within each section, findings related to each treatment component are submitted according to the aforementioned indicators. Treatment strengths for each component were then calculated based upon findings, and are discussed at the end of each section.

Quantification Of Treatment Strength for Group 5: Self-Help Independent Study (SHIS)

A total of 37 women were randomly assigned to the Self-Help Independent Study (SHIS) treatment group.

Specificity of SHIS. The activities in the SHIS were structured to enhance patients' problem solving skills, cognitive reframing skills, self-belief skills, and breast cancer information. The SHIS component focuses on cognitive and behavioral aspects.

Purity of SHIS. All subjects (N=37) randomly assigned to this group received a standardized self-study workbook of six lessons.

Frequency and Duration of SHIS. Subjects could complete lessons at their own pace, though each lesson was estimated to take an average of 90 minutes to complete. Thus, specificity, purity, duration, and frequency indicators of the SHIS component did not vary.

Intensity of SHIS. Intensity of the SHIS was measured as a proportion of completed lessons; that is the amount of information/lessons studied by the subjects. However, what the person studied may not have been perceived by them as having been useful. Thus, a second level for assessing intensity is related to whether or not the lessons taken by the subjects were perceived as having been helpful. This second level of measurement was captured by the Self-Help Activity Rating Scale (SHARS). Following are those findings:

First Level of Intensity - How many lessons did the subject complete? Nearly a third of the subjects (27%) completed all six lessons. A tenth (10.8%) of the subjects completed 3-4 lessons. More than a third (36.5%) of the subjects completed two or fewer lessons (Table 4.6).

Table 4.6 Treatment Strength of the Self-Help Independent Study (SHIS) Intervention of the SHIP.

INTENSITY 1 Numbers of Completed Lessons			**INTENSITY 2** Helpfulness Level of Lessons					
2 Lessons or less	3-4 Lessons	5-6 Lessons	Lesson1	Lesson2	Lesson3	Lesson4	Lesson5	Lesson6
36.5% n=15	10.8% n=4	27% n=10	14.05 SD 1.90 Range 10-18	22.23 SD 4.05 Range 16-30	18.71 SD 4.20 Range 12-24	23.67 SD 6.34 Range 11-31	10.22 SD 2.95 Range 7-14	11.00 SD 2.40 Range 5-13

TREATMENT STRENGTH OF SHIS - Proportion of the Intervention the Subjects Actually Receive (missing data n=19)

Mean	Median	Minimum	Maximum	SD	# Subjects Above Mean	# of Subjects Below Mean
45.75	43.92	9.46	79.72	21.14	n=9	n=9

Note: SD = Standard Deviation
Group 5 Self-Help Independent Study (SHIS) (n=37)

Second Level of Intensity - Specifically, how useful were the lessons to the subject? The average level of helpfulness of the independent study lessons to the subjects was captured by the Self-Help Activity Rating Scale (SHARS). Having a SHARS score for a particular lesson implies completion of that particular lesson. The SHARS measures the perceived level of utility of each treatment activity within the independent study lessons. Participants were asked to rate each study lesson on how helpful the activities were to them. Level of Helpfulness is represented by summing the individual lesson scores. A high score indicates that the activities were helpful to the participant. The overall level of helpfulness varied between 16 and 27 points, with a mean score of 18.31 (SD = 3.36), indicating that the lessons were helpful to the subjects. The mean score for level of perceived helpfulness of each lesson is summarized in Table 4.6.

Potency of SHIS - What is the contribution of the teachers' or interveners' education to the outcome? In this case the Self-Help Independent Study (SHIS) is self-paced and accomplished by self-study. Therefore, quantification of potency was not relevant.

Treatment Strength of SHIS - How much of the SHIS did the subjects actually receive? To answer this question, the findings of intensity are indexed to a score which indicates the strength of SHIS that the subject actually received. On average, subjects received 45.75% of the SHIS intervention (SD 21.14 %). Nine out of 37 subjects in the SHIS group (Group 5) received above the mean (45.75%) treatment strength. Nine

subjects received below the mean treatment strength score. There were 19 subjects with missing data. Details of these findings are presented in Table 4.6. This treatment strength index then was used to: 1) examine the change rate and change pattern related to the intervention; and 2) test the hypotheses.

Quantification Of Treatment Strength for Group 4: Self-Help Class (SHC)

A total of 63 women was randomly assigned to the Self-Help Class (SHC) treatment group.

Specificity of SHC. The Self-Help Class (SHC) intervention is similar to the SHIS intervention, except that the SHC was delivered to the subjects by trained teachers. Thus, the SHC was also focused on the cognitive and behavioral aspects of the psychoeducational interventions.

Purity of SHC. Classes were conducted by teachers according to the written teachers' guide. The teachers' guide was standardized, with a script and time allocation for each lesson. Class sessions were audio-taped to monitor for adherence to protocol.

Frequency and Duration of SHC. The SHC intervention consisted of six consecutive weekly classes of 60 to 150 minute class protocols. Thus, specificity, purity, duration, and frequency indicators of the SHIS intervention did not vary.

Intensity of SHC. Intensity of the SHC was measured by proportion of classes attended; that is the amount of information/classes studied by the subjects. In addition, what was studied by the patients was not necessarily useful to them. Thus, a second level

for assessing intensity is a determination of just how helpful the lessons taken by the subjects were. This second level of specific measurement was captured by the Self-Help Activity Rating Scale (SHARS). Following are those findings:

First Level of Intensity - At a global level, how many classes did the subject attend? More than half (58.7%) of the subjects attended five or more classes, while 19% attended three to four classes. Very few (1.6%) subjects attended one to two classes. Findings are summarized at Table 4.7.

Second Level of Intensity - At a more specific level, how useful were the classes to the subject? The levels of helpfulness of classes to the subjects were captured by the Self-Help Activity Rating Scale (SHARS). Participants were asked to rate each class on how helpful the class activities were to them. Level of helpfulness is represented by summing the individual activity scores. A high score indicates that the activity was helpful to the participant. The overall level of helpfulness varied between 12 and 27 points, with a mean score of 18.86 (SD = 3.10) indicating that the classes were helpful to the subjects. The mean level of perceived helpfulness for each class is summarized in Table 4.7.

Potency of SHC - What is the contribution of the teachers' or interveners' education to the outcome? Over the SHIP project period, a total of six trained teachers conducted the SHC intervention of the SHIP. Teachers included: four nurses, a social worker, and a counselor, all with varied formal education degree levels. The strength of

the Self-Help Class (SHC) treatment is more potent if, for example, the teacher has a masters degree versus bachelors degree (**potency**). A panel of experts (n=5), the members of which had backgrounds in oncology, intervention research, or program evaluation, was asked to rate the potency level of teachers with Ph.D. degree, masters degree, or lesser education. All respondents (n=5, 100% agreement) indicated that teachers' educational degree levels impact the potency of the Self-Help Class minimally. Thus, a potency indicator is not relevant to this study.

Treatment Strength of SHC - How much of the Self-Help Class did the subjects actually receive? To answer this question, the findings of intensity are indexed for each individual to indicate the strength of SHC the subject actually received. On average, subjects in the SHC group (Group 4) received 53.95% of the intended treatment (SD 22.38%). Out of 63 subjects in the SHC treatment group, 32 subjects received above the mean score for treatment strength. A smaller number of subjects (n=16) received below the mean score for treatment strength. There was missing data for 15 subjects. Details of these findings are presented at Table 4.7. This treatment strength index then was used in: 1) the next step which examined change pattern and change rate in relation to intervention; and 2) the last step which tested hypotheses.

Table 4.7 Treatment Strength of the Self-Help Class (SHC) Intervention of the SHIP.

INTENSITY 1 Number of Classes Attended			**INTENSITY 2** Helpfulness Level of Classes					
2 Lessons or Less	3-4 Lessons	5-6 Lessons	Class1	Class2	Class3	Class4	Class5	Class6
1.6% n=1	19% n=12	58.7% n=37	15.09 SD 1.90 Range 12-18	25.34 SD 3.45 Range 13-30	21.11 SD 3.58 Range 13-27	27.08 SD 4.02 Range 18-33	11.60 SD 2.03 Range 8-15	13.10 SD 1.69 Range 10-15

TREATMENT STRENGTH OF SHC - Proportion of the Intervention the Subjects Actually Received
Missing Data n=15

Mean	Median	Minimum	Maximum	SD	# of Subjects Above Mean	# of Subjects Below Mean
53.95	62.16	7.43	87.84	22.38	n=32	n=16

Note: SD = Standard Deviation
Group 4 - Self-Help Class (SHC), n=63

Quantification Of Treatment Strength for Group 3: Uncertainty Management (UM)

A total of 68 women was randomly assigned to the Uncertainty Management (UM) treatment group.

Specificity of UM - The activities of UM intervention were centered around 1) introducing and enhancing strategies for managing uncertainties, 2) providing necessary information, and 3) promoting self-care. Uncertainty Management illustrates the cognitive and psychological interventions of the SHIP study.

Purity of UM - Nurse client managers interacted with subjects according to the Standardized Assessment and Intervention Guide.

Frequency and Duration of UM - Nurse client managers spent an average of 21 minutes (Range nine to 41 minutes) on the phone with the subjects weekly for six weeks. Thus, specificity, purity, duration, and frequency indicators of the UM intervention did not vary.

Intensity of UM -The Intensity of the Uncertainty Management intervention was captured using four methods. Because the phone contacts were specific to each participant, the strength of the UM intervention was gauged in each specific case by the **number of telephone contacts** between the nurse client mangers and the participants. Treatment strength of the SHC intervention was also captured by a measure of **satisfaction level** using the Access to Nurse Case Manager questionnaire.

First Level of Intensity - How many phone contacts did the subject make/receive during the Uncertainty Management intervention period? On average, each subject had 10 contacts (range two to 47) with nurse-client managers by phone. Over half (51.48%) of the subjects had nine or less contacts with the nurse-client managers. More than a third (39.7%) of the subjects had 10 to 19 contacts with the nurse-client managers. About ten percent (10.3%) had more than 20 contacts during the intervention period. Findings are summarized in Table 4.8.

Second Level of Intensity - How satisfied was the subject with the nurse-client manager and the Uncertainty Management (UM) intervention? Every two weeks during the six-week Uncertainty Management intervention, participants were asked to rate their satisfaction regarding interactions with their nurse-client managers. Level of satisfaction for each subject is represented by summing the satisfaction scores for two weeks, four weeks, and at completion of the UM intervention. Using a five-point scale, a high score indicates that the interactions were satisfactory to the participant. The overall level of satisfaction varied between two and five points, with a mean score of 4.36 (SD = .56) indicating that phone contacts with nurse-client managers were very satisfactory for most subjects (69.1%). Levels of satisfaction are summarized in Table 4.8.

Potency of UM - What was the contribution of the nurse-client managers' education to the outcome? A total of four trained nurses with either bachelors or masters educational preparation delivered the UM intervention during the entire SHIP study.

Based on the findings related to potency, as mentioned above, the potency indicator was not relevant in this present study.

Treatment Strength of UM - How much Uncertainty Management did the subjects actually receive? To answer this question, the findings from intensity are indexed to each individual in order to indicate the strength of UM the subject actually received. On average, subjects from the UM group (Group 3) received 45.23% of the intended treatment (SD 24.05). Out of 68 subjects, nearly half (n=31) received above the average treatment strength. Another half (n=36) received below average treatment strength. Details are reported at Table 4.8. The Treatment Strength Index then was used in: 1) the next step which examined the change rate and change pattern in relation to the intervention; and 2) the last step which then tested the hypotheses.

Quantification Of Treatment Strength for Group 2: Combined SHIS and UM

A total of 30 women were randomly assigned to this combined treatment group of SHIS and UM.

Specificity, Purity, Frequency, and Duration of SHIS/UM - The Self-Help Independent Study (SHIS) and Uncertainty Management (UM) interventions were combined as specified above. Hence, treatment strength indicators such as specificity, purity, frequency, and duration did not vary.

Intensity of SHIS/ UM - Intensity of the combined SHIS/UM intervention was captured at two levels: 1) number of lessons completed, and number of phone contacts

Table 4.8 Treatment Strength of the Uncertainty Management (UM) Intervention of the SHIP.

INTENSITY 1 Number of Phone Contacts			**INTENSITY 2** Helpfulness Level of Phone Contacts				
9 or Less Contacts	10-19 Contacts	20 or More Contacts	1 Not Satisfied	2 Slightly Satisfied	3 Satisfied	4 Very Satisfied	5 Extremely Satisfied
51.48% n=35	39.7% n=27	10.3% n=7	0%	1.47% n=1	14.7% n=10	69.1% n=47	13.2% n=9
TREATMENT STRENGTH of UM - Proportion of the Intervention the Subjects Actually Received Missing Data n=1							
Mean	Median	Minimum	Maximum	SD	# Subjects Above Mean	# Subjects Bellow Mean	
45.23	42.38	3.57	100.00	24.05	n=31	n=36	

Note: SD = Standard Deviation
Group 3 - Uncertainty Management (UM), n=68

with nurse-client manager; and 2) helpfulness level of lessons completed, and subjects' satisfaction with the UM treatment.

First Level - Less than half of the subjects (43.7%) completed five or more lessons, and a nearly equal number of subjects (43.4%) had 10-19 contacts with the nurse-client managers. Details of findings are summarized at Table 4.9.

Second Level - This level of assessment was done similarly as were the SHC and UM components. The levels of helpfulness of classes to the subjects were captured by the Self-Help Activity Rating Scale (SHARS). The overall level of helpfulness varied between 11 and 27 points, with a mean score of 18.30 (SD = 3.36) indicating that the lessons were helpful to the subjects.

Level of satisfaction for each subject is represented by summing the satisfaction scores for two weeks, four weeks, and at completion of SHC/UM intervention. The overall level of satisfaction varied between two and five points, with a mean of 4.36 (SD = .56) indicating that phone contacts with nurse-client managers were very satisfactory to most subjects (58.1%). Detailed information on Levels of Helpfulness and Levels of Satisfaction are summarized at Table 4.9.

Potency of SHIS/UM - What is the contribution of the nurse-client managers' education to the outcome? Although various nurse client managers, with various levels of education (bachelors and masters degrees), were involved, potency was determined as not relevant to this study.

Treatment Strength of SHIS/UM - How much of SHIS/UM did subjects actually receive? To answer this question, the findings from intensity of SHIS and intensity of UM are indexed to each individual in order to indicate the strength of SHIS/UM the subject actually received. Subjects in this group received 50.85% of the intended intervention (SD 20.14). Moreover, half the subjects received above average (46%, =14), and half received below average scores for the treatment strength (43.3%, n=13). There were missing data for three subjects. Details related to SHIS/UM treatment strengths are presented at Table 4.9. This treatment strength index then was used to examine change rate and change pattern relative to the intervention; and then to test hypotheses.

Quantification Of Treatment Strength for Group 1: Combined SHC and UM

A total of 43 women was randomly assigned to this combined treatment group of SHC and UM.

Specificity, Purity, Frequency, and Duration of SHC/UM - The Self-Help Class (SHC) and Uncertainty Management (UM) interventions were combined as specified above. Hence, treatment strength indicators such as specificity, purity, frequency, and duration did not vary.

Intensity of SHC/UM - Intensity of the combined SHC/UM intervention was captured at two levels: 1) number of classes attended, and number of phone contacts with

Table 4.9 Treatment Strength of the Combined Self-Help Independent Study (SHIS) and Uncertainty Management (UM) Intervention of the SHIP.

INTENSITY 1 of SHIS/UM Number of Classes Attended			**INTENSITY 2 of SHIS/UM** Helpfulness Level of Classes					
2 Lessons or Less	3-4 Lessons	5-6 Lessons	Lesson 1	Lesson 2	Lesson 3	Lesson 4	Lesson 5	Lesson 6
16.7% n=5	13.3% n=4	43.7% n=13	14.62 SD 1.4 Range 12 - 17	24.40 SD 3.3 Range 18 - 28	18.70 SD 4.2 Range 11 - 26	27.20 SD 3.5 Range 21-33	11.27 SD 1.8 Range 8-13	11.90 SD 1.3 Range 10-14
INTENSITY 1 of SHIS/UM Number of Phone Contacts			**INTENSITY 2 of SHIS/UM** Helpfulness Level of Phone Contacts					
9 or Less Contacts	10-19 Contacts	20 or More Contacts	1 Not Satisfied	2 Slightly Satisfied	3 Satisfied	4 Very Satisfied	5 Extremely Satisfied	
40% n=12	43.4% n=13	3.4% n=1	0%	2.3% n=1	32.5% n=14	58.1% n=25	2.3% n=1	
TREATMENT STRENGTH of SHIS/UM - Proportion of the Intervention the Subjects Actually Received (missing data n=3)								
Mean	Median	Minimum	Maximum	SD	# Subjects Above Mean	# Subjects Below Mean		
50.85	50.94	19.76	97.48	20.14	n=14	n=13		

Notes: SD = Standard Deviation
Group 2 SHIS/UM (n=30)

nurse-client managers; and 2) helpfulness level of attended classes, and satisfaction with the UM intervention.

First Level - The majority of subjects attended five or more classes (58.3%), and had nine or fewer contacts by phone with the nurse-client managers (53.5%). Details of findings are summarized at Table 4.10.

Second Level - This level of assessment was done similarly to the separate SHC and UM interventions. The level of helpfulness of classes to the subjects was captured by the Self-Help Activity Rating Scale (SHARS). The overall level of helpfulness varied between 11 and 27 points, with a mean score of 18.31 (SD = 3.36).

Level of satisfaction for each subject is represented by summing the satisfaction scores for two weeks, four weeks, and at completion of the SHC/UM intervention (Table 4.10). The overall level of satisfaction varied between two and five points, with a mean score of 4.36 (SD = .56), indicating that phone contacts with nurse-client managers were very satisfactory to most subjects (69.1%).

Potency of SHC/UM - What is the contribution of the teachers' and nurse-client managers' education to the outcome? Similar to the SHC and UM interventions, teachers' and nurse-client managers' educational degree level impact was judged as minimal by the panel of experts. Thus, the potency indicator was not relevant to this study.

Treatment Strength of SHC/UM (Table 4.10) - How much of the SHC/UM did subjects actually receive? To answer this question, the findings from intensity of SHC and UM are indexed for each individual in order to indicate the strength of SHC/UM the subjects actually received. On average, subjects assigned to the combined SHC/UM group (GROUP 'A') received 44.01% of the intended treatment (SD 16.97). There were as many subjects who received above average treatment strength (48.8%, n=21) as those who received below average treatment strength (51.2%, n=22).

Quantification Of Treatment Strength for Group 6: Natural Learning Condition Group (NLC)

A total of 66 women was randomly assigned to the Natural Learning Condition (NLC) group. As theorized, these women engaged in learning on their own once they were diagnosed with breast cancer. Participants in this group were allowed to seek care, information, and help on their own, as well as receive care as usual. According to the substantive theory that guided the SHIP study, women in the NLC group were also expected to change over time. To monitor these changes, the subjects in the NLC group were asked to rate whether or not their ability to care for self, and their knowledge of breast cancer were improved by interacting with care providers. They are also were asked to rate their satisfaction level with the care they received, using a scale from one to five.

Table 4.10 Treatment Strength of the Combined Self-Help Class (SHC) and Uncertainty Management (UM) Intervention of the SHIP.

INTENSITY 1 of SHC/UM Number of Classes Attended			**INTENSITY 2 of SHC/UM** Helpfulness Level of Classes					
2 Classes or Less	3-4 Classes	5-6 Classes	Class 1	Class 2	Class 3	Class 4	Class 5	Class 6
2.3% n=1	25.6% n=11	58.3% n=25	14.84 SD 2.57 Range 8-18	24.96 SD 2.93 Range 18-30	20.54 SD 3.21 Range 4-27	26.04 SD 5.10 Range 14-33	11.87 SD 1.69 Range 9-15	12.23 SD 2.10 Range 8-15
INTENSITY 1 of SHC/UM Number of Phone Contacts			**INTENSITY 2 of SHC/UM** Helpfulness Level of Phone Contacts					
9 or Less Contacts	10-19 Contacts	20 or More Contacts	1 Not Satisfied	2 Slightly Satisfied	3 Satisfied	4 Very Satisfied	5 Extremely Satisfied	
53.5% n=23	32.6% n=14	7% n=3	0%	2.3% n=1	32.5% n=14	58.1% n=25	2.3% n=1	
TREATMENT STRENGTH of SHC/UM - Proportion of the Intervention the Subjects Actually Received (missing data n=0)								
Mean	Median	Minimum	Maximum	SD	# Subjects Above Mean		# Subjects Below Mean	
44.01	44.00	15.65	82.26	16.97	n=21		n=22	

Notes: SD = Standard Deviation
Group 1 SHC/UM (n=43)

On average, the subjects experienced a treatment level of 3.69 (SD .88) on a scale of one to five. Only about 3% (n=2) were not very confident in caring for themselves. Most subjects were 'confident' in caring for themselves (36.4%, n= 24). A large proportion of the subjects rated themselves as 'extremely' confident (27.3%, n= 18). This treatment level was used to model the change process for the Natural Learning Condition/Control group (Table 4.11).

Table 4.11 Treatment Strength of the Natural Learning Condition (NLC)/Control Group.

'Usual' Treatment Strength of NLC/Control Group- Helpfulness Level of the 'Usual' Care (n=66)				
1 Not Satisfied	2 Slightly Satisfied	3 Satisfied	4 Very Satisfied	5 Extremely Satisfied
0%	3.03% n=2	15.15% n=10	36.36% n=24	27.27% n=18

CHANGE: RATE AND PATTERN

The emphasis of this study is on individual differences in change, growth, and decline over time, and of proximal outcomes and distal outcome derived from the SHIP interventions. Subjects who participated in the SHIP interventions were expected to change, over time, in outcome variables such as 'enabling skills', 'self-help', 'psychological adjustment', 'uncertainty', and 'well-being'. 'Enabling skills' were examined at the sub-levels of 'belief-in-self', 'cognitive reframing', and 'problem solving'. The SHIP interventions were designed to accelerate individuals' growth in

'self-help', 'enabling skills', and managing 'uncertainty', thus adjustment to illness, and ultimately improved perceived 'well-being'. Therefore, the efficacy and effectiveness of the SHIP interventions is the degree to which the interventions can alter the normal trajectory that exists unexposed to the SHIP.

Data were collected at six data points: baseline (T_0), post-SHIP interventions (T_1), three months later (T_2), after six months (T_3), after nine months (T_4), and after 12 months (T_5). Post-interventions data were collected roughly three months after baseline data collection. Thus, data points were evenly spaced at three month intervals. Change rate in this present study was calibrated over a one year period.

In order to represent variables in a meaningful way, the mean score was computed and weighted for each individual at each data point. Individuals' weighted mean scores were then used in Growth Curve Analysis to obtain individuals' intercept (initial status) and slope (change rate) for each dependent variable (Appendix E). Recall that slope represents change rate, while the category directions (-, +) represent change pattern. Proximal and distal dependent variables of interest in this present study are: 'enabling skills', 'self-help', 'uncertainty', ' management of uncertainty', 'psychological adjustment', and 'well-being'.

In this section, findings of change rate and change patterns at group level, as related to treatment efficacy, are presented. Findings are organized according to the treatment groups: Self-Help Independent Study (SHIS/Group 5), Self-Help Class (SHC/

Group 4), Uncertainty Management (UM/Group 3), SHIS/UM/Group 2), SHC/UM/Group 1), and Natural Learning Condition (NLC/Group 6).

Change Rates and Change Patterns in Both Proximal Outcomes and Distal Outcome for All Groups

At group level, the change pattern of proximal outcomes in all groups was as expected except for SHC/UM, SHIS/UM, and SHIS groups. The change pattern in 'belief-in-self' was positive, except in the SHIS/UM group. The change pattern 'cognitive reframing' was positive, except in the SHC/UM group. The change pattern 'problem solving' was positive, except in the SHIS related groups. The change pattern 'self-help' was positive, except in the SHIS/UM group. Whereas, the change patterns of uncertainty and psychological adjustment were consistently negative, as expected across all groups. Change patterns of 'uncertainty' and 'psychological adjustment' were negative.

Changes in distal outcome were mixed with a positive pattern of change, as predicted in all treatment groups, except for the SHIS related groups. Detailed information is included at Table 4.12.

Mean slope (group level) for all groups per each outcome variable demonstrates variations of change among groups. These findings are illustrated at Figure 4.1a to Figure 4.1g.

Table 4.12 Summary of Change Rate and Change Pattern for All Groups on Proximal Outcomes and Distal Outcome

	Group 1 **SHC/UM** n=37	Group 2 **SHIS/UM** n=23	Group 3 **UM** n=60	Group 4 **SHC** n=50	Group 5 **SHIS** n=27	Group 6 **NLC** n=54
PROXIMAL OUTCOMES						
Belief in Self						
Slope	.97	-1.35	2.12	.82	.26	.49
Intercept	56.24	62.61	61.68	58.54	60.60	61.93
Cognitive Reframing						
Slope	-.14	.63	.39	**.60***	.18	-.99
Intercept	72.42	73.20	73.94	74.51	73.38	76.29
Problem Solving Slope	.46	-.01	**1.27***	.21	-.38	-.76
Intercept	66.70	67.27	66.02	70.17	69.10	66.37
Self-Help						
Slope	**2.99***	-.90	1.37	**3.02***	1.22	.60
Intercept	63.60	74.26	71.42	63.53	67.96	73.49
Uncertainty						
Slope	-1.57	-.82	-3.09	-1.95	-1.39	-1.66
Intercept	38.25	31.76	38.48	33.17	30.52	32.60
Psychological Adjustment						
Slope	-.08	-.04	-.06	-.05	-.02	-.01
Intercept	1.87	1.86	1.71	1.85	1.49	1.61
DISTAL OUTCOME						
Well-Being						
Slope	.31	-.01	.17	.78	-2.51	-1.35
Intercept	74.13	75.81	77.62	71.26	80.39	79.96

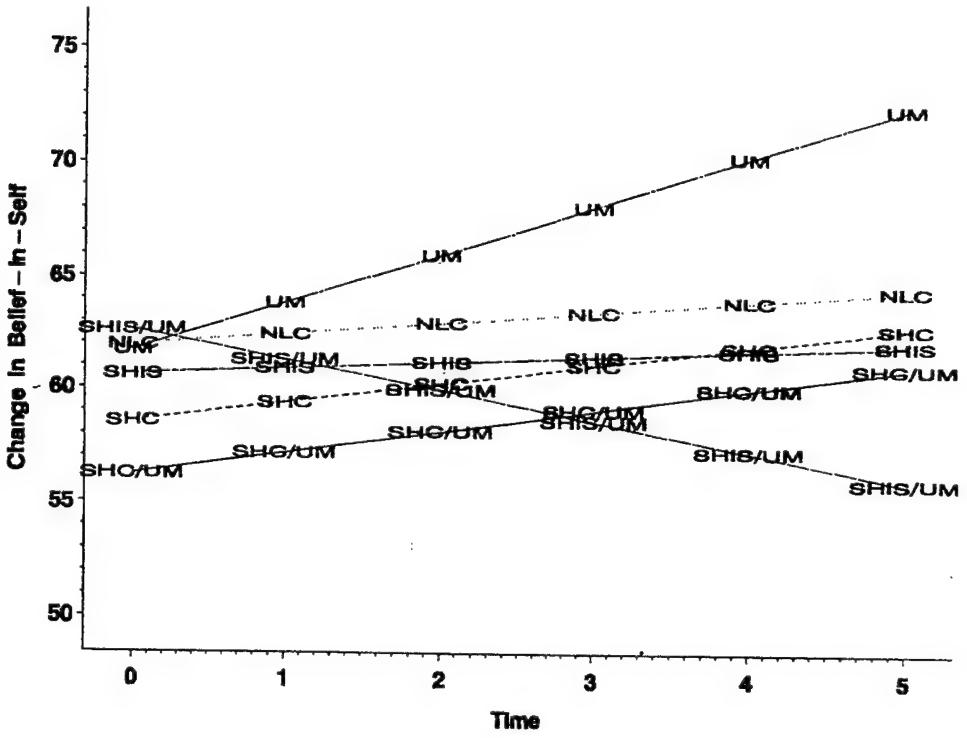
Notes: SHC = Self-Help Class
SHIS = Self-Help Independent Study
UM = Uncertainty Management
NLC = Natural Learning Condition/Control Group
*Significant Statistical Difference compared to Natural Learning Condition Group.

Group Level Change for Belief-in-Self' (Figure 4.1a) - All groups entered into SHIP interventions at the same level (mean of 60.60 ±2.00) for 'belief-in-self, except for the SHC/UM treatment group (mean of 56.24). Change patterns were all positive, except for the SHIS/UM treatment group (-1.350). Change rates were moderate (.262 to 2.123), with the steepest change rate belonging to the UM treatment group (2.123). However, the UM group's change rate for 'belief-in-self' **was not statistically significant** when compared to the natural learning condition/control group.

Group Level Change for 'Cognitive Reframing' (Figure 4.1b) - All groups entered into SHIP interventions at the same level (mean of 72.69 ±1.80) for 'cognitive reframing'. Change patterns were mostly positive (.18 to .63), except for the SHC/UM treatment group (-.14). The Natural Learning Condition (NLC/Control) group experienced a moderate decline (-.99) in 'cognitive reframing' skills over time. When compared to the Natural Learning Condition/Control group, only the SHC treatment group demonstrated a **statistically significant** change in 'cognitive reframing' (t=3.20, p=.08).

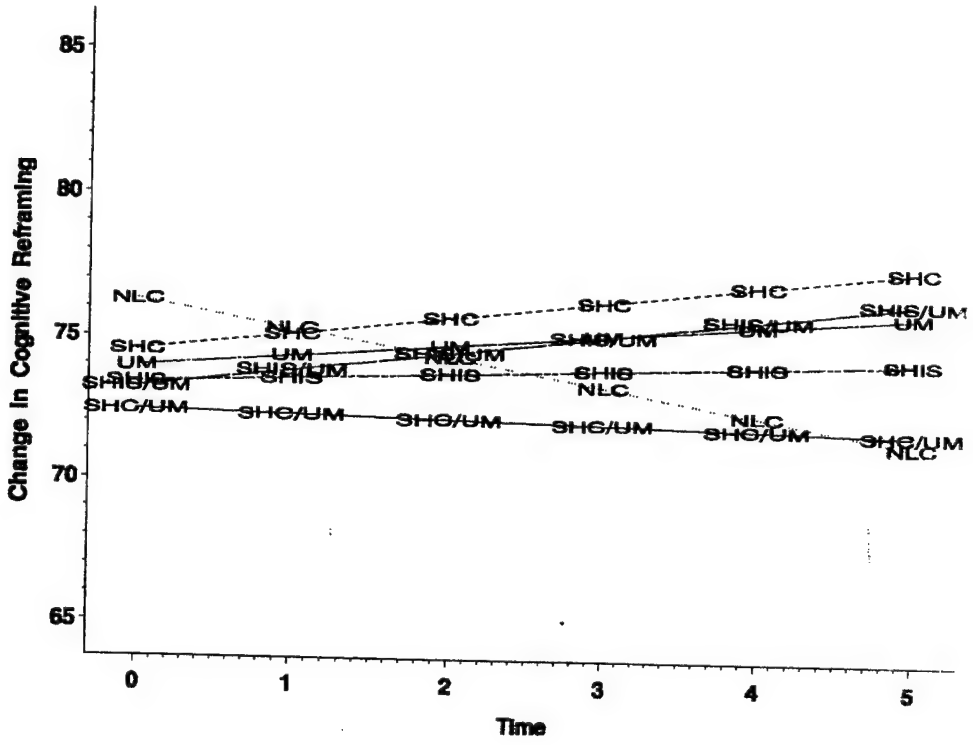
Group Level Change of 'Problem Solving' (Figure 4.1c) - All groups entered into SHIP interventions at the same level (mean of 68 ±.2.00) for 'problem solving' skills. Change patterns were mixed. The UM treatment group had the highest gain (1.27), and the control group had the steepest decline (-.76). The change rate in 'problem solving' of

Figure 4.1a Group Level Change of 'Belief in Self' for All Treatment Groups



Notes:
5 = SHIS = Self-Help Independent Study
4= SHC = Self-Help Class
3 = UM = Uncertainty Management
2 = SHIS/UM = Self-Help Independent Study plus Uncertainty Management
1 = SHC/UM = Self-Help Class plus Uncertainty Management

Figure 4.1b Group Level Change of 'Cognitive Reframing' for All Treatment Groups



Notes:
5 = SHIS = Self-Help Independent Study
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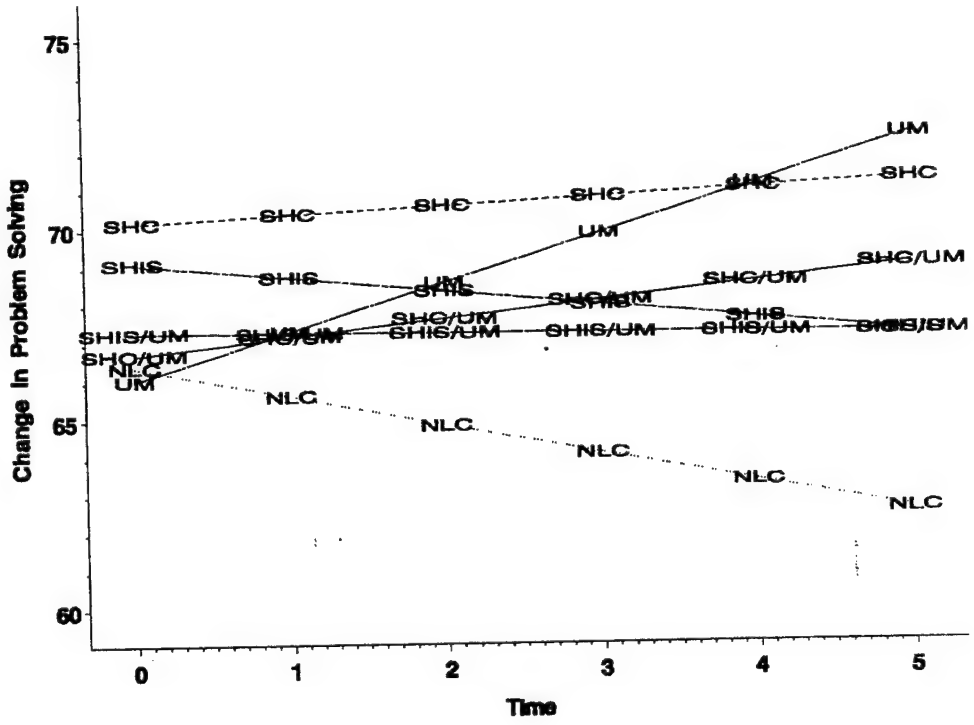
3 = UM = Uncertainty Management
2 = SHIS/UM = Self-Help Independent Study plus Uncertainty Management
1 = SHC/UM = Self-Help Class plus Uncertainty Management

Figure 4.1c Group Level Change of 'Problem Solving' for All Treatment Groups



Notes:
5 = SHIS = Self-Help Independent Study
4= SHC = Self-Help Class
3 = UM = Uncertainty Management
2 = SHIS/UM = Self-Help Independent Study plus Uncertainty Management
1 = SHC/UM = Self-Help Class plus Uncertainty Management

the UM group revealed a **statistically significant difference** between it and the control group (t=4.46, p=.04).

Group Level Change in 'Self-Help' (Figure 4.1d) - Entrance levels for 'self-help' were more varied (mean of 63.53 to 74.26). Groups with a lower entry level for 'self-help' (SHC/UM: 63.60; SHC: 63.53; SHIS: 67.96) had the expected positive change pattern (SHC/UM: 2.99; SHC: 3.02; SHIS; 1.22). Whereas the SHIS/UM group with the highest entry level (mean of 74.26) for 'self-help' had a negative change pattern (-.90). Change in 'self-help' for the SHC group (t=4.39, p=.04) and the SHC/UM group (t=3.95, p=.05) **were statistically significant** in their difference from the control group.

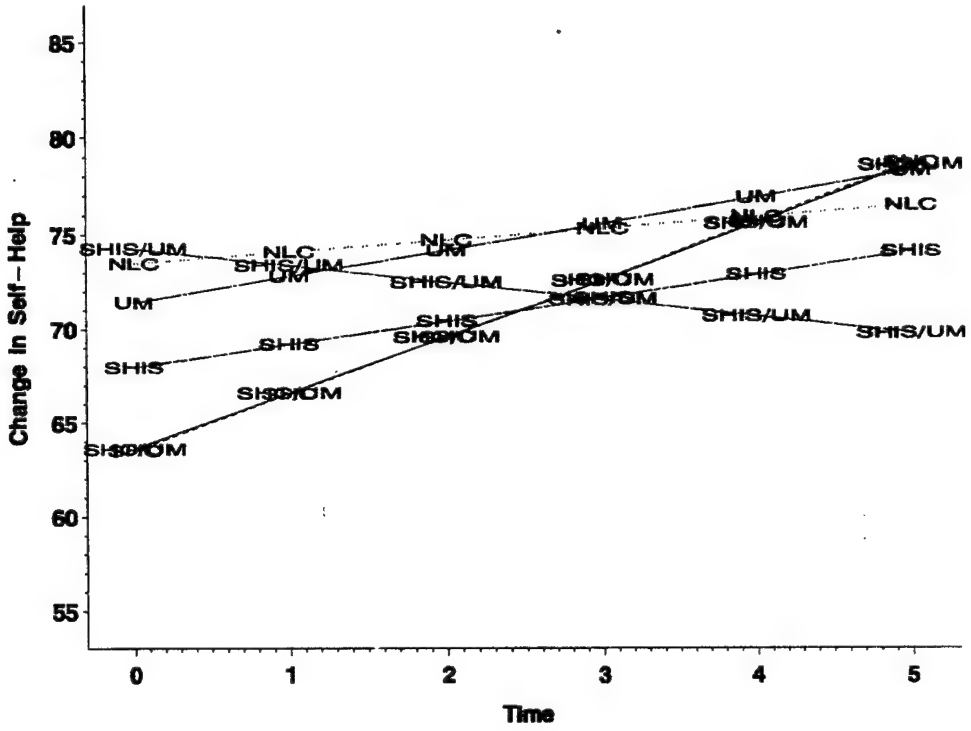
Group Level Change in 'Uncertainty' (Figure 4.1e) - All groups showed a negative change pattern in uncertainty level, even though they had a different entry level (range 30.52 to 38.48). Standing out was the UM group which began with the highest baseline uncertainty level (38.48), and then demonstrated the steepest change rate in uncertainty level (-3.088). However, the change **was not statistically significant** compared to the natural learning condition/control group.

Group Level Change in 'Psychological Adjustment' (Figure 4.1f) - Entry levels for psychological adjustment were varied (range 1.49 to 1.87). All treatment groups displayed change in psychological adjustment in a negative direction which was expected by the researcher. The control group, however, remained roughly unchanged (-.01).

There was **no statistically significant** difference between treatment groups and natural learning condition/control group.

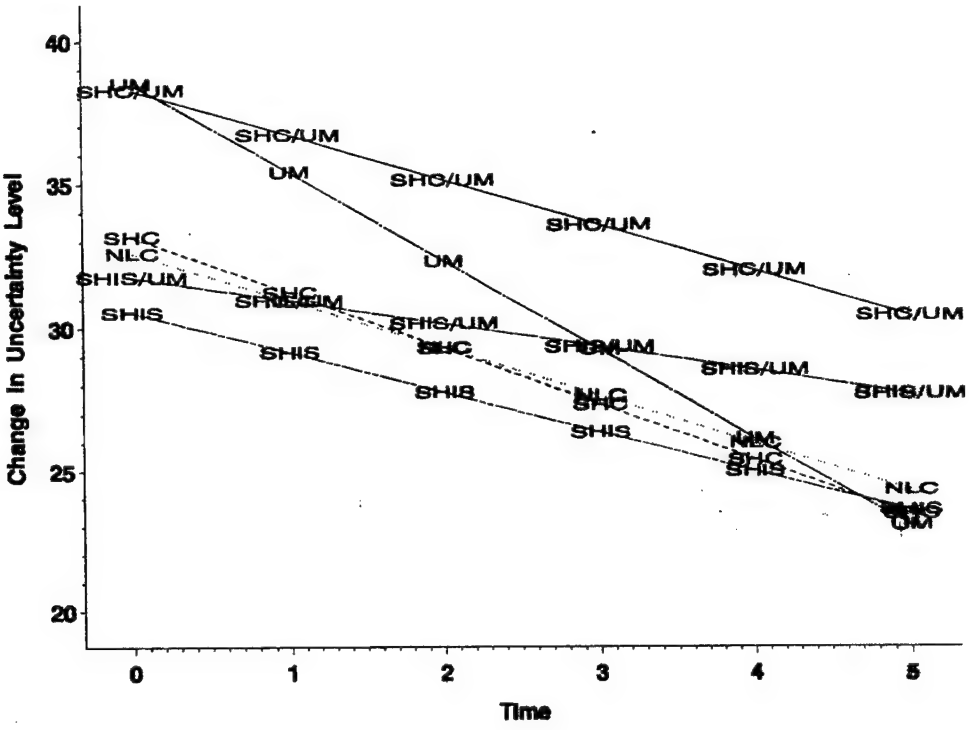
Group Level Change in 'Well-Being' (Figure 4.1g) - 'Well-being' was indexed by nine items from the Index of Well-Being Scale. The baseline level of 'well-being' varied from 71.26 to 80.39. All treatment groups except the SHIS/UM group exhibited a gain/positive pattern in 'well-being' level; although the change rate was slow. As opposed to improvement or gain in 'well-being' level, both the control group and the SHIS/UM group had a negative change pattern for 'well-being'. There was **no statistically significant** difference between treatment group and natural learning condition/control group.

Figure 4.1d Group Level Change in 'Self-Help' for All Treatment Groups



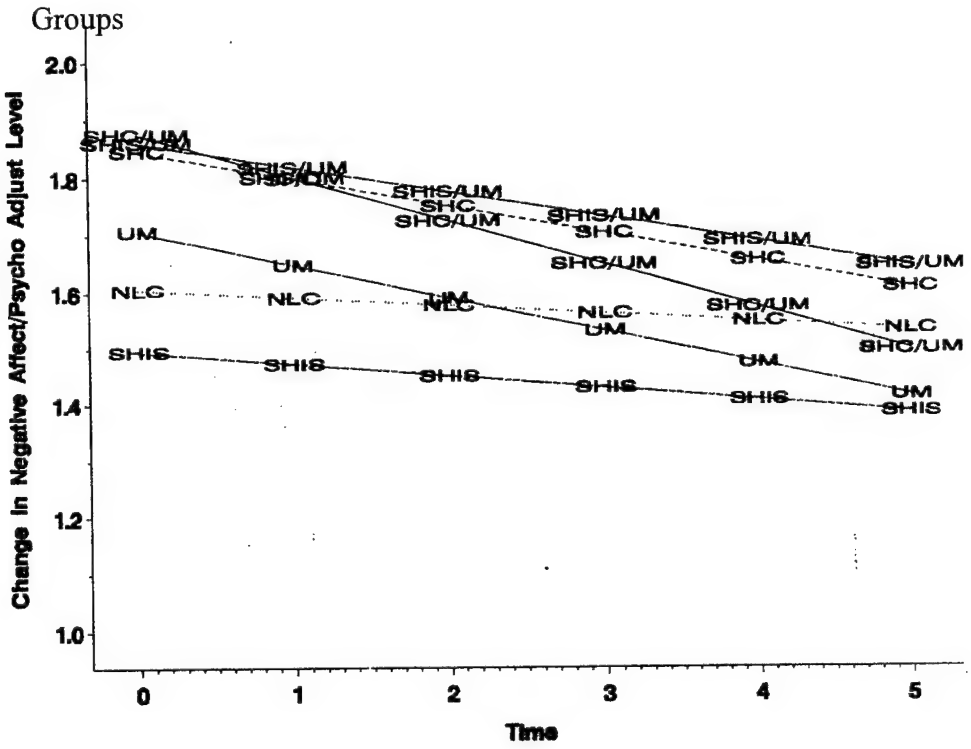
Notes:
5 = SHIS = Self-Help Independent Study
4= SHC = Self-Help Class
3 = UM = Uncertainty Management
2 = SHIS/UM = Self-Help Independent Study plus Uncertainty Management
1 = SHC/UM = Self-Help Class plus Uncertainty Management

Figure 4.1e Group Level Change in 'Uncertainty' for All Treatment Groups



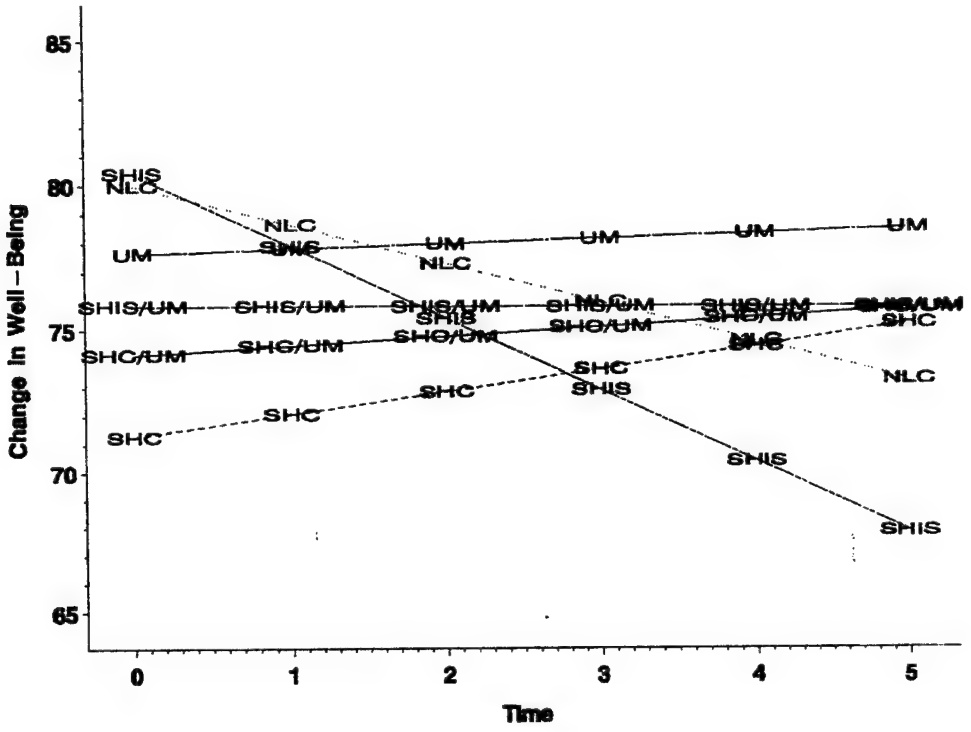
Notes:
5 = SHIS = Self-Help Independent Study
4= SHC = Self-Help Class
3 = UM = Uncertainty Management
2 = SHIS/UM = Self-Help Independent Study plus Uncertainty Management
1 = SHC/UM = Self-Help Class plus Uncertainty Management

Figure 4.1f Group Level Change in 'Psychological Adjustment' for All Treatment



Notes:
5 = SHIS = Self-Help Independent Study
4= SHC = Self-Help Class
3 = UM = Uncertainty Management
2 = SHIS/UM = Self-Help Independent Study plus Uncertainty Management
1 = SHC/UM = Self-Help Class plus Uncertainty Management

Figure 4.1g Group Level Change in 'Well-Being' for All Treatment Groups



Notes:
5 = SHIS = Self-Help Independent Study
4= SHC = Self-Help Class
3 = UM = Uncertainty Management
2 = SHIS/UM = Self-Help Independent Study plus Uncertainty Management
1 = SHC/UM = Self-Help Class plus Uncertainty Management

Group 5 - Self-Help Independent Study (SHIS) Group.

The sample for growth curve analysis was 27 subjects. At group level, subjects in the SHIS group experienced modest (-.02) to moderate (-2.51) change rate in proximal outcomes and distal outcome over the one year data collection period (Table 4.13). There were three positive change patterns: 'belief-in-self' (.26), 'cognitive reframing' (.18), and 'self-help' (1.22); four negative change patterns: 'problem solving' (-.38), 'uncertainty' (-1.39), 'psychological adjustment' (-.02), and 'well-being' (-2.51).

Table 4.13 Group Level Change Pattern and Change Rate in Proximal Outcomes and Distal Outcome of the SHIS Treatment Group (n=27).

Change: Rate & Pattern in	Mean of Slope	Range of Slope	Standard Deviation of Slope
Enabling Skills:			
Belief-in-Self	.26	-15.67 to 12.75	7.49
Cognitive Reframing	.18	-13.05 to 10.15	5.42
Problem Solving	-.38	-12.73 to 9.96	5.78
Self-Help	1.22	-16.53 to 13.62	7.95
Uncertainty	-1.39	-13.47 to 12.27	5.74
Psychological Adjustment'	-.02	-.40 to .45	.19
Well-Being	-2.51	-35.56 to 19.39	10.84

Thirty five percent (35.14%, n=13) of the subjects displayed a negative change pattern for 'self-help'; only 21.62% demonstrated the expected positive change pattern. Those who demonstrated a positive change pattern in 'self-help' (21.62%, n=8) were younger (by roughly 10 years) than the non-improved group. This **difference was statistically significant** (t= 4.61, p=.05). Table 4.12 shows that change rates varied

within the groups as reflected in the 'range of slope'. Plottings of individual slopes are provided in Appendix F.

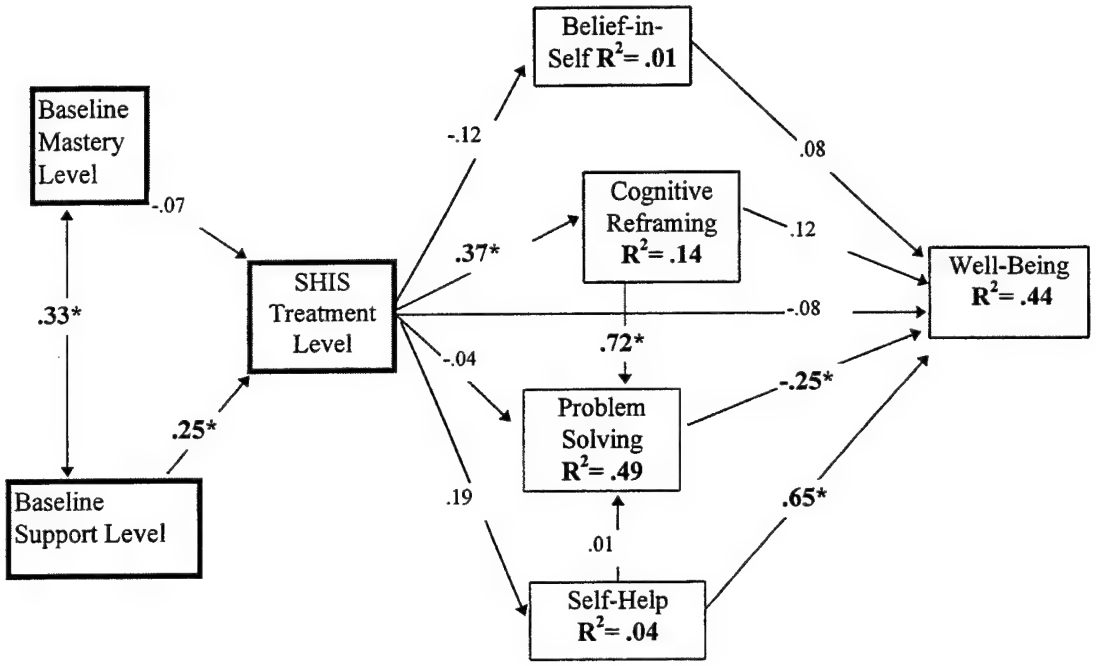
Taking into account that age moderated the SHIS treatment affect on outcomes, there was still no direct effect of SHIS treatment level on outcomes. The effects of SHIS treatment on the outcomes of 'enabling skills', 'self-help', and 'well-being' were examined next using individuals' data, and structural equation modeling (SEM). The SEM models all variables in the equation simultaneously, including covariations among specified variables. The Self-Help Independent Study level directly improved 'cognitive reframing' (β=.37, $p<.10$), which in-turn directly improved 'problem solving' (β= .72, $p<.10$). However, the more improvement in 'problem solving', the less improvement the subjects reported for 'well-being' (β= -.25, $p<.10$). Additionally, the higher support level the subjects had at entry into SHIS treatment, the more SHIS treatment they participated in. Two proximal outcomes: 'problem solving' (β= -25, $p<.10$) and 'self-help' (β= .65, $p<.10$) had a statistically significant direct effect on 'well-being' (Figure 4.2). As a whole, the treatment framework (figure 4.5) for SHIS explained 44% of variance in change of 'well-being' with the good model fit index (CFI= .95). That is, the model fits the data. The CFI indicates that treatment affected outcomes as specified.

Group 4 - Self-Help Class (SHC) Treatment Group

Growth Curve Analysis was used to examine the 50 subjects in the SHC group. At group level, subjects in the SHC group experienced modest (-.05) to moderate (3.02)

change rate in proximal outcomes and distal outcome over a one year period. There were five positive change patterns: 'belief-in-self' (.82), 'cognitive reframing' (.60), 'problem solving' (.21), 'self-help' (3.02), and 'well-being' (.78); and two negative change patterns: 'uncertainty' (-1.95) and 'psychological adjustment' (-.04). At group level, changes in 'cognitive reframing' (t=3.20, p=.08) and 'self-help' (t=4.39, p=.04) **were statistically significant** when compared to the natural learning condition/control group. All change patterns were in the expected direction (Table 4.14). Change rates within the group also varied widely. Individual change rates are plotted and provided in Appendix F.

Figure 4.2 Treatment Framework for Self-Help Independent Study (SHIS) Treatment Group.



Independent Chi Square $_{(df28)}$ = 56.71, Model Chi Square$_{(df14)}$ = 15.56, CFI = ..95

Table 4.14 Group Level Change Pattern and Change Rate in Proximal Outcomes and Distal Outcome of the SHC Group (n=50)

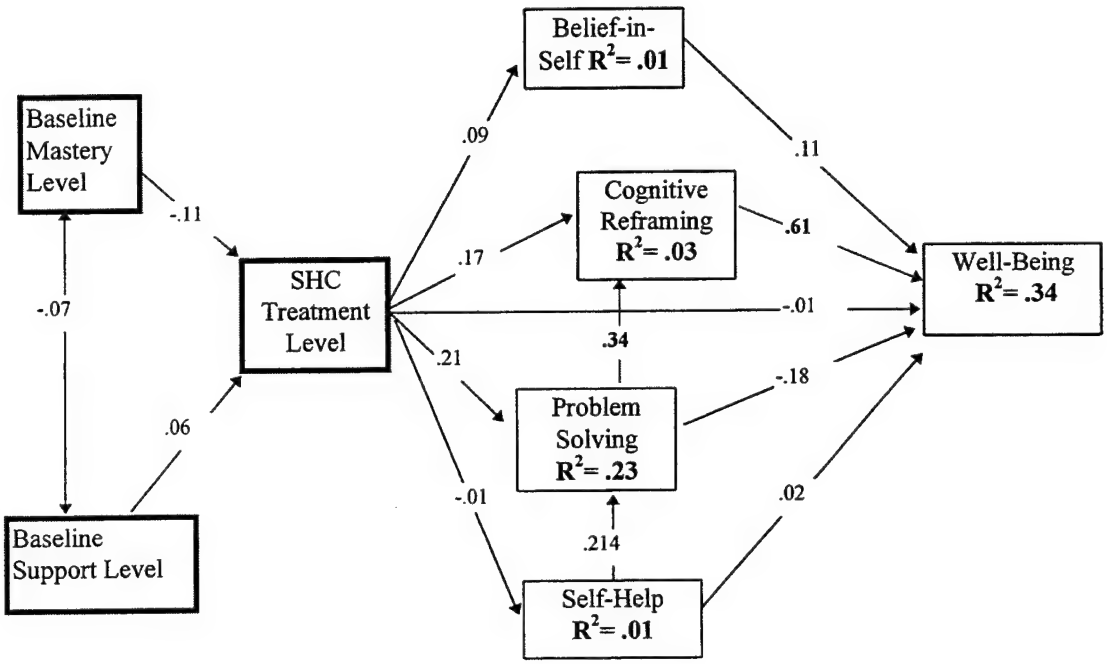
Change Pattern & Change Rate in:	Mean of Slope	Range of Slope	Standard Deviation of Slope
Enabling Skills			
Belief in Self	.82	-17.50 to 16.75	6.04
Cognitive Reframing	**.60***	-9.05 to 9.00	3.76
Problem Solving	.21	-13.82 to 13.05	4.03
Self-Help	**3.02***	-11.16 to 26.86	6.49
Level-of-Uncertainty	-1.95	-17.56 to 7.06	4.60
Psychological Adjustment	-.05	-.65 to .85	.29
Well-Being	.78	-27.67 to 15.78	6.71

* Statistically significant at $p<.10$ level when compared to natural learning condition/control group

Those who demonstrated a positive change pattern in 'self-help' (25.40%, n=16) had a slightly lower initial mastery level (66.4) than the non-improved group (75.3). This difference was not significant when compared to the non-improved (negative change pattern) group.

The effects of SHC treatment on the outcomes of 'enabling skills', 'self-help', and 'well-being' were examined next using individuals' data and structural equation modeling (SEM). The SEM models all the variables in the equation simultaneously, including covariations among specified variables. The Self-Help Class level did not directly improve any of the proximal outcomes, as was hypothesized. However, greater improvement in 'problem solving' directly influenced greater improvement in 'cognitive reframing' ($\beta= .34$, $p<.10$), which in-turn directly affected change in 'well-being' ($\beta= .61$, $p<.10$). As a whole, the treatment framework (Figure 4.3) for SHC explained 34% of

Figure 4.3 Treatment Framework for the Self-Help Class (SHC) Treatment Group.



Independent Chi Square $_{(df28)}$ =92.12, Model Chi Square $_{(df14)}$ =53.84, CFI = .38

variance in change of 'well-being' with the poor model fit index (CFI= .38). The model did not fit the data. A low CFI indicates that there were other factors involved in the transformation process of treatment on outcomes.

Group 3 - Uncertainty Management (UM) Treatment Group

At group level, subjects in the UM group (n=60) also experienced a modest (-.06) to high (-3.09) change rate in proximal outcomes and distal outcome. There were five positive change patterns: 'belief-in-self' (2.12), 'cognitive reframing' (.39), 'problem solving' (1.27), 'self-help' (1.37), and 'well-being' (.17); and two negative change patterns: 'uncertainty' (-3.09) and 'psychological adjustment' (-.06). The Change in 'problem solving' **was statistically significant in its difference** from the control group (t=4.46, p=.04). More details can be found at Table 4.15. Individual changes varied widely. Individuals' change rate and pattern are provided in Appendix F.

Table 4.15 Change Rate and Change Pattern at Group Level for Proximal Outcomes and Distal Outcome of UM Group (n=60)

Change Pattern & Change Rate	Mean of Slope	Range of Slope	Standard Deviation of Slope
Enabling Skills			
Belief in Self	2.12	-18.84 to 23.20	7.42
Cognitive Reframing	.39	-19.55 to 21.75	6.10
Problem Solving	**1.27***	-20.68 to 8.96	5.15
Self-Help	1.3	-27.44 to 29.72	8.23
Uncertainty	-3.09	-27.58 to 12.68	6.93
Psychological Adjustment	-.06	-.90 to .55	.25
Well-Being	.17	-24.95 to 22.17	7.40

* Statistically significant at p<.10 level when compared to natural learning condition/control group

Significant relationships among UM treatment, proximal outcomes, and distal outcome are reported in a later section of this chapter under the heading of GROUP 'B'. Of those reporting a decline in 'negative affect' (42.65%, n=29), which denotes an improvement in psychological adjustment, there was also a lower baseline mastery level (63.60) as compared to the non-improved group (79.7). This difference **was statistically significant** (t= 2.85, df=1, p=.07).

Group 2 - SHIS/UM Treatment Group

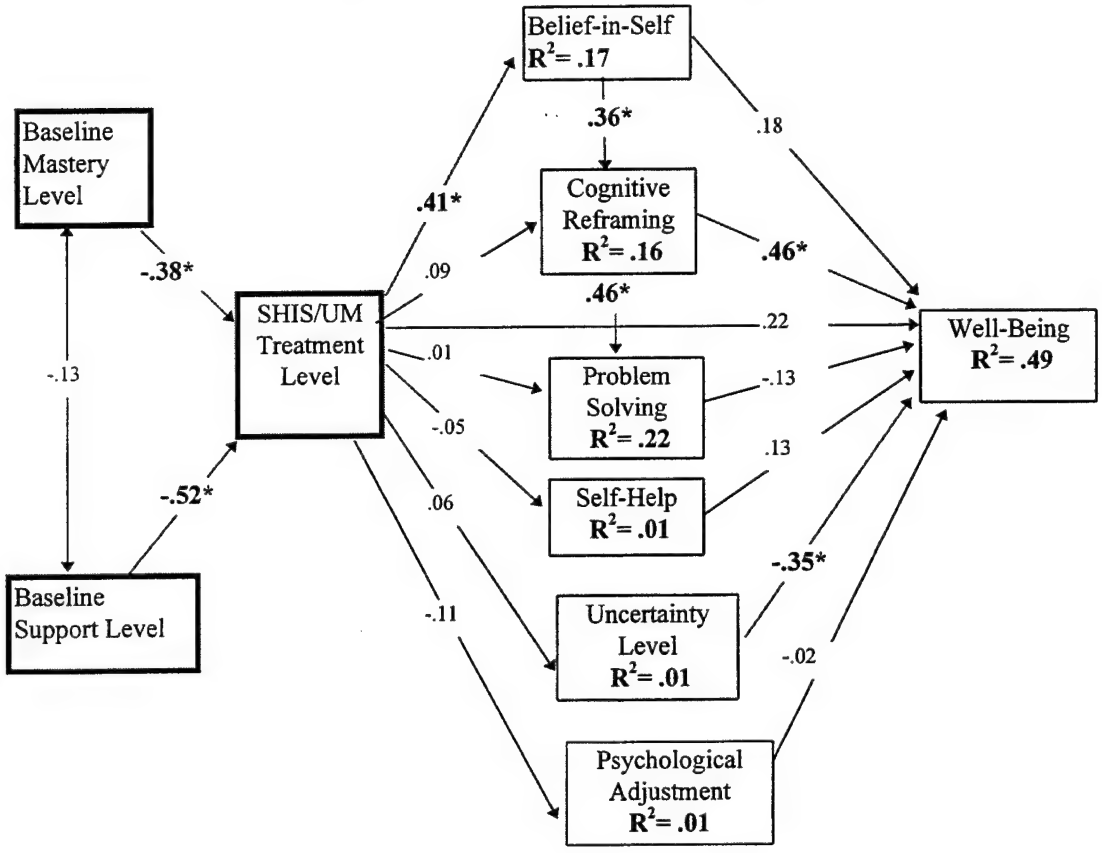
At group level, subjects in the SHIS/UM group (n=23) experienced modest change rates (-.01 to -1.35) in both proximal outcomes and distal outcome. All change patterns were negative, except for change in 'cognitive reframing'. These descriptive findings are presented at Table 4.16. Individuals' change rates varied widely within the SHIS/UM group (Appendix F). For example, four out of 23 subjects had extreme decline in 'belief-in-self', while others in the group experienced slight gain, or remained unchanged. Similarly, six out of 23 subjects in the SHIS/UM group had an extreme drop in 'self-help', while other subjects experienced slow improvement in 'self-help'. A large number of outliers relative to the small sample size in the SHIS may account for the negative group mean score for change in 'belief-in-self' and 'self-help'.

Table 4.16 Change Pattern and Change Rate at Group Level in Proximal Outcomes and Distal Outcome of the SHIS/UM Group (n=23)

Change Pattern & Change Rate :	Mean of Slope	Range of Slope	Standard Deviation of Slope
Enabling skills			
Belief in Self	-1.35	-17.83 to 14.25	8.41
Cognitive Reframing	.63	-11.85 to 11.85	5.70
Problem Solving	-.01	-7.24 to 7.55	3.86
Self-Help	-.90	-15.67 to 10.08	6.60
Uncertainty	-.82	-9.20 to 6.99	4.18
Psychological adjustment	-.04	-.95 to .90	.43
Well-Being	-.01	-23.12 to 17.17	7.52

Next, the effects of SHIS/UM treatment on the outcomes of: 'enabling skills', 'self-help', 'uncertainty', 'psychological adjustment', and 'well-being' were examined using individuals' data, and by use of structural equation modeling (SEM). The Self-Help Independent Study plus Uncertainty Management (SHIS/UM) treatment level directly improved change in 'belief-in-self' (β= .41, $p<.10$), which in-turn positively improved 'cognitive reframing' (β= .36, $p<.10$) and eventually improved 'well-being' (β= .46, $p<.10$). Change in 'cognitive reframing' also led to faster change in 'problem solving' (β= .46, $p<.10$); however, change in 'problem solving' did not significantly change 'well-being'. Although the SHIS/UM treatment level did not change the 'uncertainty' level at a statistically significant degree, change in 'uncertainty', however led to improved 'well-being' (β= -.35, $p<.10$). As a whole, the treatment framework (Figure 4.4) for SHIS/UM explained 49% of variance in change of 'well-being' with the

Figure 4.4 Treatment Framework for the Self-Help Independent Study Plus Uncertainty Management (SHIS/UM) Treatment Group.



Independent Chi Square $_{(df45)}$ =60.38, Model Chi Square $_{(df27)}$ =18.86, CFI = 1.00

excellent model fit index (CFI= 1.00). The model fits the data perfectly. The high CFI indicates that the treatment affects outcomes as specified.

Additionally, women who had a lower baseline mastery level participated more in the SHIS/UM treatment (β= -.38, $p<.10$). Women who had a lower support level at entry also participated more in the SHIS/UM treatment. Those demonstrating a positive change pattern in 'belief-in-self' (36.33%, n=11) had a lower initial mastery level (70.6/100 versus 80.0/100). These differences were **not statistically different** from the non-improved (negative change pattern) group. Evidence of baseline mastery level moderating the effect of SHIS/UM level on change in 'belief-in-self' was lacking. Finally, there **was significant** negative correlation (r= -.55, $p<.05$) between length from diagnosis to SHIS/UM intervention versus change in 'problem solving' skills. The further the women were from diagnosis, the less change in 'problem solving' skills they demonstrated. The average numbers of days from diagnosis to SHIS/UM was 99 (SD 74).

Group 1 - SHC/UM Treatment Group

At group level, subjects in the SHC/UM group (n=37) experienced modest (-.08) to moderate (2.99) change rate in proximal outcomes and distal outcome over the one year period (Table 4.17). Table 4.17 shows four positive change patterns: 'belief in self' (.93), 'problem solving' (.46), 'self-help' (2.99), and 'well-being' (.31); and three negative change patterns: 'cognitive reframing' (-.14), 'uncertainty'(-1.57), and

'psychological adjustment' (-.08). Change in 'self-help' **was statistically significant** in difference from the control group (t=3.95, p=.05). Table 4.17 shows that individuals' change rates were mixed (Appendix F).

Table 4.17 Change Rate and Change Pattern at Group Level in Proximal Outcomes and Distal Outcome in the SHC/UM Group (n=37)

Change rate & Change Pattern:	Means of Slope	Range of Slope	Std.Dev. of Slope
Enabling Skills			
Belief in Self	.93	-25.00 to 13.50	6.12
Cognitive Reframing	-.14	-8.35 to 7.25	3.25
Problem Solving	.46	-16.68 to 10.64	4.89
Self-Help	**2.99***	-12.15 to 22.70	6.11
Uncertainty	-1.57	-26.15 to 16.94	6.54
Psychological Adjustment	-.08	-.70 to .38	.25
Well-Being	.31	-11.34 to 7.72	4.18

* Statistically significant at p<.10 level when compared to natural learning condition/control group

Those who demonstrated a positive change pattern in 'cognitive reframing' (44.19%, n=19) tended to be younger (54.7 years versus 56.4 years), and had lower initial mastery level (65.5/100 versus 74.25/100). These differences were **not significantly different** from the non-improved (negative change pattern) group.

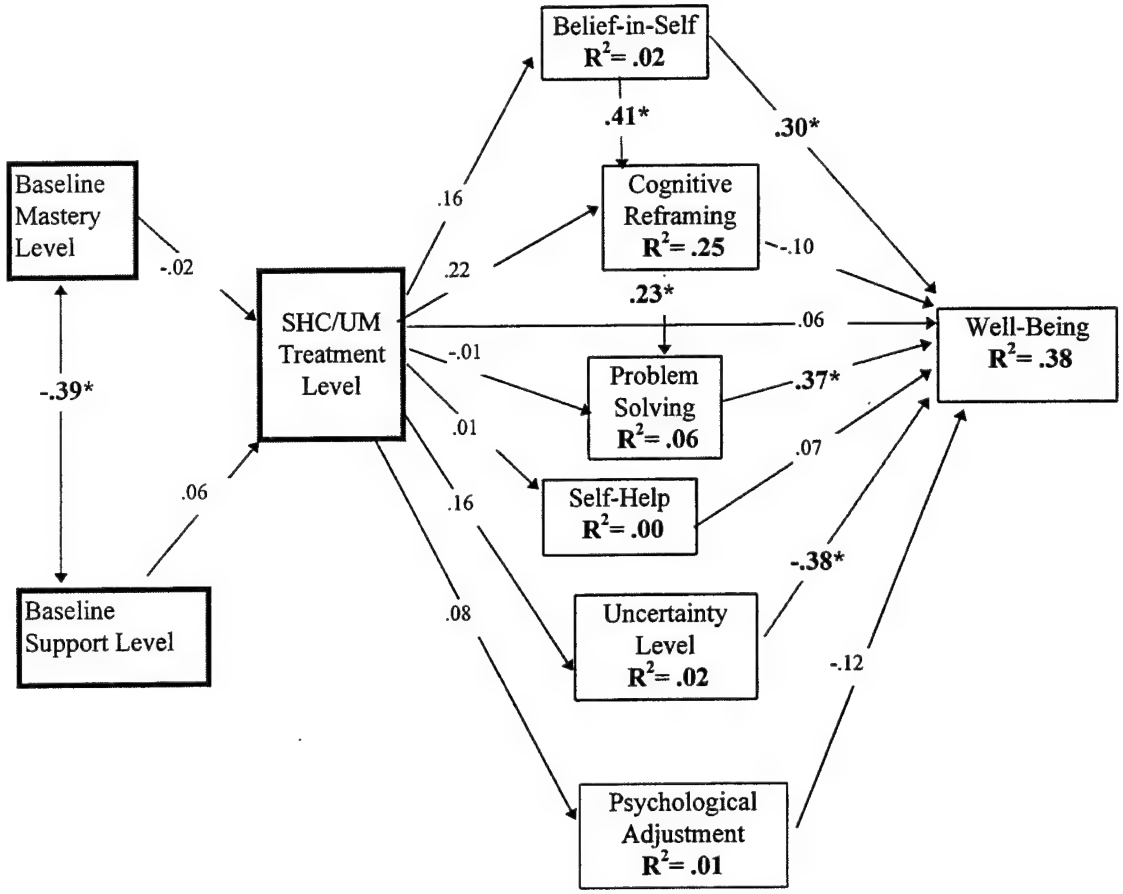
Next the effects of the SHC/UM treatment on outcomes of: 'enabling skills', 'self-help', 'uncertainty', 'psychological adjustment', and 'well-being' were examined using individuals' data , and structural equation modeling (SEM). The Self-Help Class plus Uncertainty Management (SHC/UM) treatment level did not directly affect any of the proximal outcomes, as hypothesized. Among proximal outcomes, change in 'belief-in-

self' led to improvement in 'cognitive reframing' (β= .41, p<.10), and then 'problem solving' (β= .23, p<.10). Both change in 'belief-in-self' (β= .30, p<.10) and 'problem solving' (β= .37, p<.10) directly influenced improvement in 'well-being'. Moreover, a drop in 'uncertainty' level also directly improved the change in 'well-being' (β= -.38, p<.10). Baseline mastery level negatively covaried with the baseline support level (β= -.39, p<.10); however, this covariation did not influence the subjects' level of participation in the SHC/UM treatment. As a whole, the treatment framework (Figure 4.5) for SHC/UM explained 38% of variance in change of 'well-being' with the poor model fit index (CFI= .35). The model did not fit the data, indicating that there were other factors involved in the transformation process of treatment on outcomes.

Group 6 - Natural Learning Condition (NLC)/ Control Group.

At group level, subjects in the NLC group experienced modest change rates in proximal outcomes and distal outcome. There were two positive change patterns: 'belief-

Figure 4.5 Treatment Framework for Self-Help Class Plus Uncertainty Management (SHC/UM) Treatment Group.



Independent Chi Square $_{(df45)}$ = 72.99, Model Chi Square $_{(df27)}$ = 45.31 , CFI =.35

in-self' (.49) and 'self-help' (.60). Other outcomes had negative change patterns: 'cognitive reframing' (-.99), 'problem solving' (-.76), 'uncertainty' (-1.66), 'psychological adjustment' (-.01), and 'well-being' (-1.35). These descriptive findings are presented at Table 4.18.

Table 4.18 Change Rate and Change Pattern at Group Level in Proximal Outcomes and Distal Outcome of the Natural Learning Condition/ Control Group.

Change Rate & Change Pattern	Mean of Slope	Range of Slope	Standard Deviation of Slope
Enabling Skills			
Belief-in-Self	.49	-14.86 to 11.42	4.79
Cognitive Reframing	-.99	-10.75 to 14.80	5.11
Problem Solving	-.76	-18.87 to 8.96	5.09
Self-Help	.60	-14.10 to 14.15	5.29
Uncertainty	-1.66	-33.90 to 18.23	6.79
Psychological Adjustment	-.01	-.65 to .45	.21
Well-Being'	-1.35	-19.89 to 22.95	6.57

The only change in proximal outcomes that was statistically significant was 'psychological adjustment' (β = .31, p=<.10). Change in 'psychological adjustment', in-turn, led to change in 'well-being' (β = -.32, p=<.10). Change in 'cognitive reframing' led to positive change in 'problem solving' (β = .55, p=<.10). Change in 'self-help' led to change in 'well-being' (β = .48, p=<.10) (Figure 4.9). Moreover, the longer the women had been diagnosed with breast cancer, the less change in uncertainty they perceived (r= -.32, p<.05). The average term from diagnoses to entry into the SHIP study was 140 days. As time passed, the women were more likely to be familiar with breast cancer therapies, options, etc.

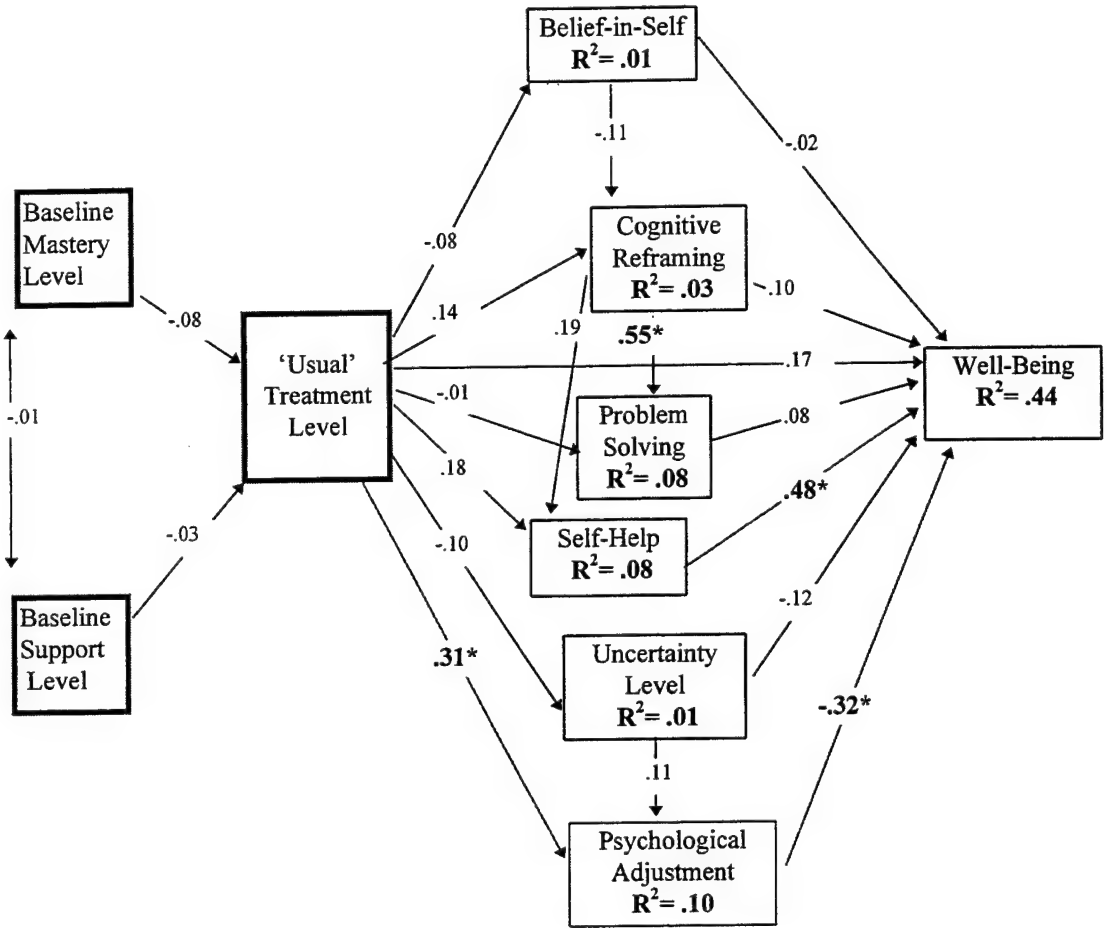
As a whole, the treatment framework (Figure 4.6) of 'usual' treatment explained 44% of variance in change of 'well-being' with a fit index of .75 (CFI= .75). The model did not fit the data fully, indicating that there were other factors involved in the transformation process of treatment on outcomes.

In summary, change rate and change pattern in outcomes were widely varied among subjects within each treatment group as reflected in Table 4.12 through Table 4.18. At group level, changes in outcomes were generally in the expected direction. Lastly, three treatment groups (SHC/UM, UM, and SHIS) experienced statistically significant change compared to the control group in three proximal outcomes: 'cognitive reframing', 'problem solving', and 'self-help'. In the following section, results related to the proposed hypotheses are presented and organized according to treatment group.

Hypotheses Testing

The treatment framework (Figure 2.2), derived from substantive and treatment theories, provides an organizational framework for evaluating SHIP interventions. Derived from this treatment framework, 22 hypotheses were generated to validate the efficacy and effectiveness of the SHIP interventions. The statistical method of Structural Equation Modeling (SEM) was used to test the direct and indirect effects of. SHIP interventions on proximal outcomes and distal outcome. In addition, moderating effects of the conditioning factors on subjects' responses to SHIP interventions were investigated by using SEM.

Figure 4.6 'Usual' Treatment Framework for the Natural Learning Condition/Control Group.



Independent Chi Square $_{(df45)}$ = 98.53, Model Chi Square $_{(df25)}$ = 38.26 , CFI =.75

The sample size was adequate during the treatment phase (T_0 to T_2), and sharply decreased in its adequacy during the follow-up phase (T_3 to T_5). As discussed earlier, not all subjects got a chance to continue participation during the follow-up phase. Data collection points were missed due to interrupted funding for the project, not due to other processes such as self-selection. Although growth curve modeling is efficient in saving subjects with missing data points, small sample size still is a concern. Sample size was as low as 23 subjects (SHIS/UM), while another group had as high as 60 subjects (UM). Small sample size may destabilize parameter estimations, thus combining treatment groups with similar 'treatment specificity' was used to counter the problem of small sample size of some groups.

Subjects from groups that have similar treatment "specificity" were pooled in order to increase statistical power. For example, the categories Self-Help Independent Study (SHIS) plus Uncertainty Management (UM), and the Self-Help Class (SHC) plus Uncertainty Management (UM) had exact "treatment specificity", and thus were combined as (**GROUP 'A'**). The "treatment specificity" of the Uncertainty Management (UM) component was psychological and therefore distinct from others; thus, it remained separate as (**GROUP 'B'**). On the other hand, both SHIS and SHC were similar; thus, subjects were pooled as (**GROUP 'C'**). Lastly, the natural learning condition group was left untouched as GROUP 6. Results of hypotheses testing are reported and organized according to these groups.

Additionally, the alpha level was set at .10 for determining statistical significance effects. Only effects that accounted for at least 5% (.05) of the variance in the rate of change of outcomes are reported.

GROUP 'A': The Self-Help Independent Study (SHIS) Plus Uncertainty Management (UM) Group and the Self-Help Class (SHC) Plus Uncertainty Management (UM) Group
n=60

For this group, a total of 18 pertinent hypotheses were tested. Below, each hypothesis is restated and followed by the findings for each.

Hypothesis 1. *The initial level of personal characteristics, age, and education, may affect subjects' participation fully in the SHIP interventions.* Neither age nor education level had a statistically significant direct effect on patients' level of participation in the SHIS/UM or SHC/UM treatment.

Hypothesis 2. *Medical characteristics of therapy-related, as well as disease-related, status may affect subjects' participation fully in the SHIP intervention.* Medical characteristics consist of disease-related factors and therapy-related factors specific to the patient. As a whole, medical characteristics represent how ill patients are. Medical characteristics did not have a statistically significant direct effect on patients' level of participation in the SHIS/UM or SHC/UM treatments.

Hypothesis 3. *Participants' initial level of personal characteristics moderates the affects of SHIP interventions on proximal outcomes.* The interaction between personal characteristics (age,

education) and SHIS/UM or SHC/UM treatment did not have a statistically significant effect on changes in the level of 'belief-in-self', 'cognitive reframing', 'problem solving', 'self-help', 'uncertainty', or 'psychological adjustment'.

Hypothesis 4. *Participants' initial level of medical characteristics(therapy-related and disease-related) moderates the effect of SHIP interventions on proximal outcomes.* The interaction between medical characteristics and SHIS/UM or SHC/UM treatment did not have a statistically significant effect on changes in the level of 'belief-in-self', 'cognitive reframing', 'problem solving', 'self-help', 'uncertainty', or 'psychological adjustment'.

Hypothesis 5. *Participants' initial level of mastery moderates the affect of SHIP interventions on proximal outcomes.* The interaction between baseline mastery level and SHIS/UM or SHC/UM did not have a statistically significant effect on changes in the level of 'belief-in-self', 'cognitive reframing', 'problem solving', 'self-help', 'uncertainty', or 'psychological adjustment'.

Hypothesis 6. *Participants' initial level of social support moderates the effect of SHIP interventions on proximal outcomes*. The interaction between baseline support level and SHIS/UM or SHC/UM treatment did not have a statistically significant effect on changes in the level of 'belief-in-self', 'cognitive reframing', 'problem solving', 'self-help', 'uncertainty', or 'psychological adjustment'.

Hypothesis 7. *Participants' personal characteristics directly affect the rate of change in 'well-being'.* Personal characteristics (age, education) did not have a statistically significant direct effect on changes in the level of 'well-being'.

Hypothesis 8. *Participants' medical characteristics directly affect the rate of change in 'well-being'.* Medical characteristics did not have a statistically significant direct effect on changes in the level of 'well-being'.

Hypothesis 9. *Participants' initial level of mastery directly affect the rate of change in 'well-being'.* Initial level of mastery had a statistically significant direct negative effect (β= -.25, $p<.10$) on change in 'well-being' for women in the SHIS/UM and SHC/UM groups.

Hypothesis 10. *Participants' personal characteristics moderate the affect of SHIP interventions on distal outcome.* The interaction between personal characteristics and SHIS/UM or SHC/UM treatment did not have a statistically significant effect on changes in the level of 'well-being'.

Hypothesis 11. *Participants' medical characteristics moderate the effect of SHIP interventions on distal outcome.* The interaction between medical characteristics and SHIS/UM or SHC/UM treatment did not have a statistically significant effect on changes in the level of 'well-being'.

Hypothesis 12. *Participants' initial level of mastery moderates the effect of SHIP interventions on distal outcome.* The interaction between baseline mastery level and SHIS/UM or SHC/UM

treatment did not have a statistically significant effect on changes in the level of 'well-being'.

Hypothesis 13. *Those being in either the Self-Help Independent Study (SHIS) or Self-Help Class (SHC) will experience a change toward better 'enabling skills' (positive change pattern).* This hypothesis was not applicable for GROUP A.

Hypothesis 14. *Those being in either the Self-Help Independent Study (SHIS) or Self-Help Class (SHC) will experience a change toward more 'self-help' (positive change pattern).* This hypothesis was not applicable for GROUP A.

Hypothesis 15. *Those subjects being in Uncertainty Management (UM) experienced change toward less 'uncertainty' (negative change pattern) over time.* This hypothesis was not applicable for GROUP A.

Hypothesis 16. *Those being in Uncertainty Management (UM) experienced change toward better 'psychological adjustment', or less negative affect (negative change pattern) over time.* This hypothesis was not applicable for GROUP A.

Hypothesis 17. *Those in the combined interventions of UM and SHIS or UM and SHC will experience a change toward less negative affect (negative change pattern), less uncertainty (negative pattern of change), more self-help (positive change pattern), and better enabling skills (positive change pattern) over time.* At group level, change rate and change pattern in 'belief-in-self', 'cognitive reframing', and 'problem solving' were .05, .16, and .28 respectively. Group level changes were not statistically significant as to difference from the control group. More subjects revealed positive change patterns in all enabling skills than did the control group (Table 4.19). Individual's parameters (intercept and slope) were used to test the effect of

treatment on change in 'enabling skills'. Levels of SHIS/UM or SHC/UM treatment **had a statistically significant** positive direct effect only on changes in 'belief-in-self' (β =.27, p<.10).

The group's mean slope for 'self-help' was 1.50. Sixty-six percent (n=51) of the participants in this group showed positive change toward 'self-help'. However, the change was **not statistically significant** when compared to the control group. Details are recorded at Table 4.19. Again, individual parameters were used to test treatment effect on 'self-help'. Levels of SHIS/UM or SHC/UM treatment had **no significant direct effect** on changes in 'self-help'.

The group's mean slope for 'uncertainty' level was -1.28; pattern of change was in the expected direction. Almost twice as many subjects from the SHIS/UM or SHC/UM treatment group showed a decline in uncertainty level (52.05%) versus gain more uncertainty (30.14%). However, the change was **not statistically significant** when compared to the control group. Details are recorded at Table 4.19. Using individuals' parameters, levels of SHIS/UM or SHC/UM treatment had **no significant direct effect** on changes in 'uncertainty' level.

The group's mean slope for 'psychological adjustment' level, as measured by 'negative affect', was -.06; pattern of change was in the expected direction. Forty-one percent (41.10%) of subjects showed a decline in negative change pattern. However, the change was **not statistically significant** when compared to the control group. Details are

recorded at Table 4.19. Levels of SHIS/UM or SHC/UM treatment had no significant direct effect on changes in 'psychological adjustment' level as derived by individuals' parameters.

Table 4.19 Summary of Change in Proximal Outcomes for **GROUP 'A' (SHIS/UM** or **SHC/UM)** and **Control Group**.

Change in Enabling Skills	**GROUP 'A' SHIS/UM or SHC/UM** (n=60)	**GROUP 6 NLC or Control Group** (n=54)
Belief-in-Self	Mean .05 SD 7.10	Mean .49 SD 4.79
Negative Change Pattern	41.67% (n=25)	44.44% (n=24)
Positive Change Pattern	58.33% (n=35)	55.56% (n=30)
Cognitive Reframing	Mean .16 SD 4.32	Mean -.99 SD 5.11
Negative Change Pattern	41.67% (n=25)	55.56% (n=30)
Positive Change Pattern	58.33% (n=35)	44.44% (n=24)
Problem Solving	Mean .28 SD 4.49	Mean -.76 SD 5.09
Negative Change Pattern	43.33% (n=26)	51.85% (n=28)
Positive Change Pattern	55.00% (n=33)	48.15% (n=26)
Change in Self-Help	Mean 1.50 SD 6.53	Mean .60 SD 5.29
Negative Change Pattern	31.67% (n= 19)	40.74% (n= 22)
Positive Change Pattern	66.67% (n=40)	59.26% (n= 32)
Change in Uncertainty	Mean -1.28 SD 5.72	Mean -1.66 SD 6.79
Negative Change Pattern	52.05% (n= 38)	57.58% (n= 38)
Positive Change Pattern	30.14% (n=22)	24.24% (n= 16)
Change in Psychological Adjustment	Mean -.062 SD .33	Mean -.014 SD .21
Negative Change Pattern	41.10% (n= 30)	43.94% (n= 29)
Positive Change Pattern	28.77% (n=21)	22.73% (n=15)

Hypothesis 18. *Those participants being in any SHIP intervention component will experience change (b) toward improved 'well-being'.* At group level, subjects in either the SHIS/UM or the SHC/UM group had a change rate of .19 in 'well-being'. Table 4.20 shows that there were more subjects with positive change pattern in the 'well-being' category of GROUP 'A' (63.79%) than GROUP 6 (50.00%). The difference was not statistically significant. Levels of SHIS/UM or SHC/UM treatment had no significant direct effect on changes in 'well-being' level as modeled by individuals' parameters (intercept and slopes).

Table 4.20 Summary of Change in 'well-being' for **GROUP 'A' (SHIS/UM** or **SHC/UM)** and **Control Group**.

Change in 'well-being'	**GROUP 'A'** **SHIS/UM or SHC/UM** Mean .19 (n= 58)	**GROUP 6** **NLC or Control** Mean -1.35 (n= 54)
Negative Change Pattern	36.21% (n= 21)	50.00% (n= 27)
Positive Change Pattern	63.79% (n= 37)	50.00% (n= 27)

Hypothesis 19. *A change over time in 'enabling skills' will lead to a change in 'well-being' over time.* The change in 'belief-in-self' (β =.25, p<.10) and 'cognitive reframing' (β =.21, p<.10) had a statistically significant direct positive effect on change in 'well-being'. Change in 'belief-in-self' led to improvement in 'cognitive reframing' (β =.35, p<.10) which led to improvement in 'problem solving' (β =.31, p<.10) and 'self-help' (β =.29, p<.10).

Hypothesis 20. *A change over time in 'self-help' will lead to a change in 'well-being' over time.* Changes in 'self-help' did not directly lead to change in 'well-being'.

Hypothesis 21. *A change over time in uncertainty management will lead to a change in well-being over time.* Change in 'uncertainty' level had a statistically significant direct effect on 'well-being' ($\beta = -.42$, $p<.10$).

Hypothesis 22. *A change over time in psychological adjustment will lead to a change in well-being over time.* Change in 'psychological adjustment' did not have a significant direct effect on change in 'well-being'.

IN SUMMARY, subjects who participated in either the Self-Help Independent Study (SHIS) plus Uncertainty Management (UM) or the Self-Help Class (SHC) plus Uncertainty Management (UM) demonstrated a small gain in 'belief-in-self' (.05), a larger gain in 'cognitive reframing' (.16) and 'problem solving' (.28), and a much larger gain in 'self-help' (1.50). On the other hand, subjects in the control group (Natural Learning Condition) had either smaller gains or actual declines. As related to change in 'uncertainty' level and 'psychological adjustment' level, the subjects had a moderate decline, as hypothesized. There were also comparable changes in the control group.

For 'well-being', subjects in the SHIS/UM or SHC/UM group had a slight gain (.19); whereas, subjects in the control group declined more rapidly (-1.35) over the one year period. These changes were not statistically significant as to difference between the control group. Nonetheless, further examination reveals a clear pattern that more subjects in the treatment group than in the control group improved over time in 'enabling skills', 'self-help', and 'well-being', as hypothesized.

Significant findings related to treatment effects on proximal outcomes, and distal outcome are illustrated in Figure 4.10. Those findings are as follows:

1. The stronger the SHIS/UM or SHC/UM treatment strength, the stronger the subjects' 'belief-in-self' became (β =.27, p<.10),

2. Change in 'Belief-in-self' led to change in 'cognitive reframing (β =.35, p<.10),

3. Initial level of mastery plays a direct role in changes of 'well-being'; low initial level of mastery influenced facter change in 'well-being' (β =-.25, p<.10),

4. More change in 'cognitive reframing' led to the more change in 'problem solving' (β =.31, p<.10) and 'self-help' (β =.29, p<.10),

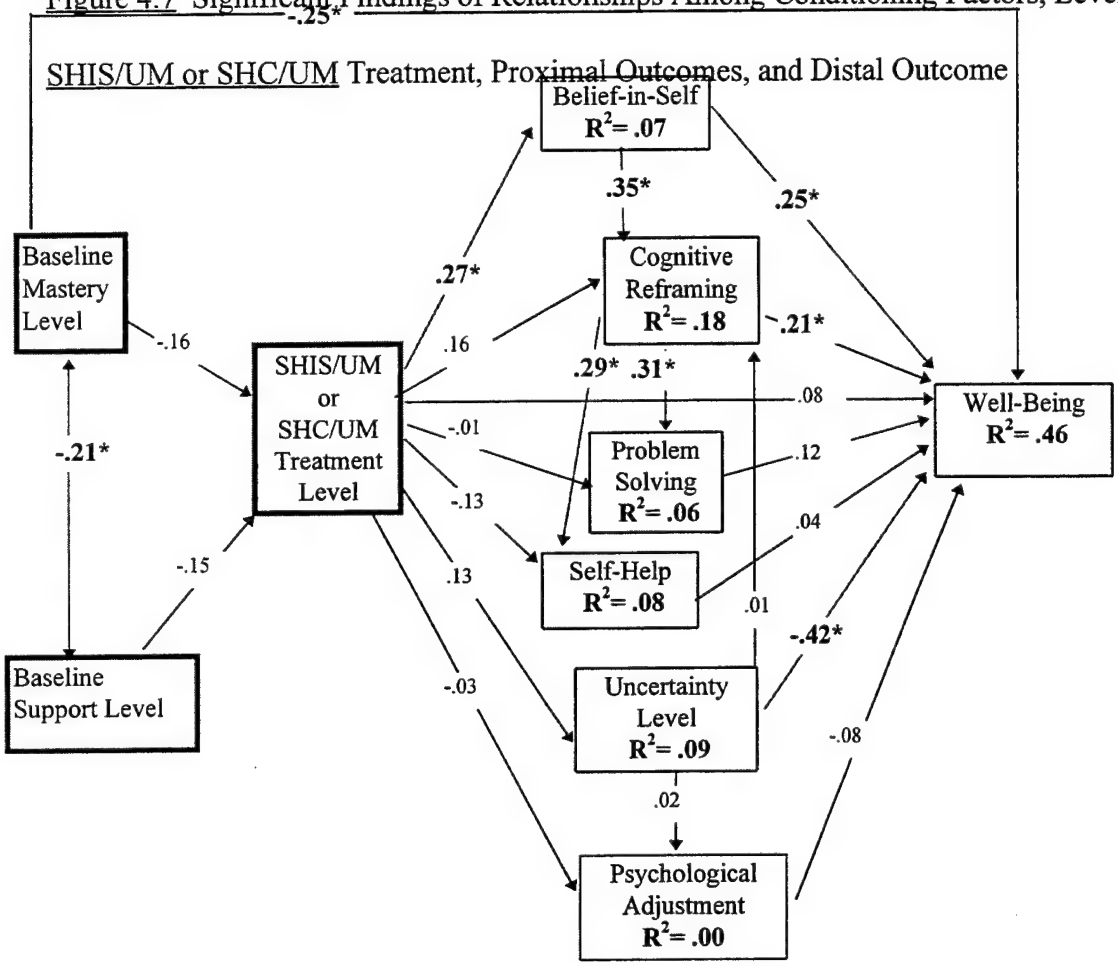
5. Change in 'cognitve reframing' also led to change in well-being (β =.21, p<.10),

6. Change in 'belief-in-self' had a statistically significant direct positive effect on change in 'well-being' (β =.25, p<.10), and

7. Change in 'uncertainty' level had a statistically significant direct negative effect on 'well-being' (β = -.42, p<.10).

As a whole, the treatment model of GROUP 'A' accounted for 46% of variance in change of 'well-being', with an excellent fit index (CFI=1.00). High CFI indicates that the SHIS/UM or SHC/UM treatment affected outcomes as specified.

Figure 4.7 Significant Findings of Relationships Among Conditioning Factors, Levels of SHIS/UM or SHC/UM Treatment, Proximal Outcomes, and Distal Outcome



Independent Chi Square $_{(df45)}$ = 80.95, Model Chi Square $_{(df23)}$ = 19.75 , CFI =1.00

GROUP 'B': The Uncertainty Management (UM) Group
n=60

For the treatment group Uncertainty Management, 17 pertinent hypotheses were tested. Findings are presented in each hypothesis section.

Hypothesis 1. *The initial level of personal characteristics, age and education, may affect subjects' full participation in the SHIP interventions.* Neither age nor education level had any statistically significant direct effect on patients' level of participation in the UM treatment.

Hypothesis 2. *Medical characteristics of therapy-related, as well as disease-related, status may affect subjects' participation fully in the SHIP interventions.* Medical characteristics did not have a statistically significant direct effect on patients' level of participation in the UM treatment.

Hypothesis 3. *Participants' initial level of personal characteristics moderates the effects of SHIP interventions on proximal outcomes.* The interaction between personal characteristics (age, education) and UM treatment did not have a statistically significant effect on targeting changes in the level of 'uncertainty', or 'psychological adjustment'.

Hypothesis 4. *Participants' initial level of medical characteristics: therapy-related and disease-related, moderates the effect of SHIP interventions on proximal outcomes.* The interaction between medical characteristics and UM treatment level did not have a statistically significant effect on targeting changes in the level of 'uncertainty', or 'psychological adjustment'.

Hypothesis 5. *Participants' initial level of mastery moderates the effect of SHIP interventions on proximal outcomes.* Rather than having a moderating effect on UM treatment targeting changes in the level of 'uncertainty', or 'psychological adjustment', the initial level of mastery (intercept) had a statistically significant negative direct effect ($\beta = -.34$, $p<.10$) on the level of UM treatment. Although women with high baseline mastery level took a lower UM treatment level, they were more satisfied (mean sastisfaction score 4.68) with the treatment they received as compared to the women in the lower baseline mastery level (mean satisfaction score 4.29). The differential satisfaction rating were statisically significant ($t= 7.16$, $p=.01$). The correlation between baseline mastery level and satisfaction with UM treatment was positive and significant at $p<.05$ level ($r= .31$). Initial level of mastery also had a statistically significant direct positive effect ($\beta =.30$, $p<.10$) on 'psychological adjustment'.

Hypothesis 6. *Participants' initial level of social support moderates the effect of SHIP interventions on proximal outcomes.* The interaction between baseline support level and UM treatment did not have a statistically significant effect on changes in the level of 'uncertainty', or 'psychological adjustment'.

Hypothesis 7. *Participants' personal characteristics directly affect the rate of change in 'well-being'.* Personal characteristics (age, education) did not have a statistically significant direct effect on changes in the level of 'well-being'.

Hypothesis 8. *Participants' medical characteristics directly affect the rate of change in 'well-being'.* Medical characteristics did not have a statistically significant direct effect on changes in the level of 'well-being'.

Hypothesis 9. *Participants' initial level of mastery directly affects the rate of change in 'well-being'.* Initial level of mastery had a no statistically significant direct effect on change in 'well-being'.

Hypothesis 10. *Participants' personal characteristics moderate the affect of SHIP interventions on distal outcome.* The interaction between personal characteristics and UM treatment level did not have a statistically significant effect on change in the level of 'well-being'.

Hypothesis 11. *Participants' medical characteristics moderate the effect of SHIP interventions on distal outcome.* The interaction between medical characteristics and UM treatment level did not have a statistically significant effect on change in the level of 'well-being'.

Hypothesis 12. *Participants' initial level of mastery moderates the effect of SHIP interventions on distal outcome.* The interaction between baseline mastery level and UM treatment level did not have a statistically significant effect on change in the level of 'well-being'.

Hypothesis 13. *Those being in either the Self-Help Independent Study (SHIS) or Self-Help Class (SHC) will experience a change toward better 'enabling skills' (positive change pattern).* This hypothesis was not pertinent to GROUP 'B'.

Hypothesis 14. *Those being in either the Self-Help Independent Study (SHIS) or Self-Help Class (SHC) will experience a change toward more 'self-help' (positive change pattern).* This hypothesis was not pertinent to GROUP 'B'.

Hypothesis 15. *Those subjects being in Uncertainty Management (UM) experienced change toward less 'uncertainty' (negative change pattern) over time.* At group level, subjects in the UM group had a change rate of -3.09 in 'uncertainty' level. The negative change pattern is consistent with hypothesis 15. Table 4.21 shows that 66% of the subjects in the treatment group had a decline in 'uncertainty'. However, there was also roughly the same improvement in the control group (70.37%). The improvement rate was **not statistically significant** ($t=1.24$, $p=.27$) between the UM group and the control group.

Individuals' parameters (intercepts and slopes) were used to test the effect of UM treatment on proximal outcomes. All variables in the model were analyzed simultaneously; thus more reflective of reality. Levels of UM treatment had a statistically significant influence on change in 'uncertainty' level ($\beta= -21$, $p<.10$); the more Um treatment the subjects partcipated in, the less uncertainty they perceived.

Table 4. 21 Summary of Group Level Change in Uncertainty Level for **GROUP 'B'** (**UM** Group) and **Control Group**.

Change in Level of Uncertainty	**GROUP 'B' Uncertainty Management Group** (n=60)	**GROUP 6 NLC or Control Group** (n=54)
	Mean -3.09 SD 6.93	Mean -1.66 SD 6.79
Negative Change Pattern	66.67% (n= 40)	70.37% (n= 38)
Positive Change Pattern	33.33% (n=20)	29.63% (n=16)

Hypothesis 16. *Those being in Uncertainty Management (UM) experienced change toward better 'psychological adjustment', or less negative affect (negative change pattern) over time.* At group level, subjects in the UM group had a change rate of -.06 in 'psychological adjustment'. The negative change pattern is consistent with hypothesis 16. Table 4.22 shows that the same number of subjects improved in both groups. Thus, improvement rate was **not statistically significant** between the UM group and the control group.

Levels of UM treatment had a statistically significant direct negative effect on change in 'psychological adjustment' ($\beta = -.25$, $p<.10$). Moreover, change in 'uncertainty' also led to more change in 'psychological adjustment' ($\beta = .48$, $p<.10$). Initial mastery level, UM treatment level, and change in 'uncertainty' explained 50% of variance in change of 'psychological adjustment'.

Table 4.22 Summary of Group Level Change in 'Psychological Adjustment' Level for the UM Group versus the Control Group.

Change in 'psychological adjustment'	**GROUP 'B' Uncertainty Management** Group (n= 60) Mean -.06 SD .246	**GROUP 6 NLC or Control Group** (n= 54) Mean -.01 SD .21
Negative Change Pattern	63.04% (n= 29)	65.91% (n= 29)
Positive Change Pattern	36.96% (n= 17)	34.09% (n= 15)

Hypothesis 17. *Those in the combined interventions of UM and SHIS or UM and SHC will experience a change toward less negative affect (negative change pattern), less uncertainty (negative pattern of change), more self-help (positive change pattern), and better enabling skills (positive change pattern) over time.* This hypothesis was not applicable for GROUP B.

Hypothesis 18. *Those subjects being in any SHIP intervention component will experience change **(b)** toward improved 'well-being'.* At group level, subjects in the UM treatment group had a change rate of .17 in 'well-being' as compared to the change rate of -1.35 in the control group. Table 4.23 shows that there were slightly more subjects (54.24%) with positive change pattern in 'well-being' than negative change pattern (45.76%). An equal number of subjects improved as did not improve in 'well-being' level in the control group. Statistically, there was no significant difference between the treatment group and the control group.

The effect of UM treatment on 'well-being' was modeled by individual's parameters (intercept and slope). Levels of UM treatment **did not have a statistically significant** direct effect on changes in 'well-being' level.

Table 4.23 Summary of Group Level Change in 'well-being' for the UM Group and Control Group.

Change in 'well-being'	**GROUP 'B'** **Uncertainty Management** Group (n= 60) Mean .17 SD 7.40	**GROUP 6** **NLC or Control Group** (n= 54) Mean -1.35 SD 6.57
Negative Change Pattern	45.76% (n= 27)	50.00% (n= 27)
Positive Change Pattern	54.24% (n= 32)	50.00% (n= 27)

Hypothesis 19. *A change over time in enabling skills will lead to a change in well-being over time.* This hypothesis was not applicable for GROUP B.

Hypothesis 20. *A change over time in self-help will lead to a change in well-being over time.* This hypothesis was not applicable for GROUP B.

Hypothesis 21. *A negative change over time in level of 'uncertainty' will lead to a positive change in 'well-being' over time.* Change in 'uncertainty' level directly and negatively affects the change level in 'well-being', and **was statistically significant** (β = -.24, $p<.10$).

Hypothesis 22. *A change over time in 'psychological adjustment' will lead to a change in 'well-being' over time.* A change in 'psychological adjustment' level, as measured by negative affect, **had a statistically significant** directly negative effect on change in the level of 'well-being' (β = -.35, $p<.10$).

IN SUMMARY, subjects who participated in the Uncertainty Management (UM) group had a greater decline in 'uncertainty' level (-3.09) than subjects in the control group (-1.66). However, the difference was **not statistically significant**. Change related to 'psychological adjustment' was roughly equal for both groups (Treatment = -.06, Control= -.01). For 'well-being', subjects in the UM group had a slight gain (.17); whereas, subjects in the control group declined more rapidly (-1.35) over the one year period.

Findings of relationships among conditioning factors, levels of UM treatments, proximal outcomes, and distal outcome are illustrated in Figure 4.8, and are as follows:

1. Initial level of mastery was much more prominent in the UM treatment group. Initial mastery level had a direct negative effect on levels of UM treatment taken by the subjects (β = -.34, $p<.10$),
2. Initial level of mastery also had a statistically significant positive direct effect on changes in 'psychological adjustment' (β =.30, $p<.10$),
3. Levels of UM treatment had a statistically negative direct effect on changes in 'uncertainty' (β = -.21, $p<.10$) and 'psychological adjustment' (β = -.25, $p<.10$),
4. More change in 'uncertainty' level led to more change in 'psychological adjustment' (β =.48, $p<.10$)
5. Change in 'uncertainty' level had a statistically significant negative direct effect on change in 'well-being' (β = -.24, $p<.10$), and

6. Change in 'psychological adjustment' had a statistically significant negative direct effect on change in 'well-being' ($\beta = -.35$, $p<.10$).

As a whole, the treatment model of GROUP 'B' accounted for 23% of variance in change of 'well-being' with an excellent fit index (CFI=.98). High CFI indicates that the UM treatment affected outcomes as specified.

GROUP 'C': The Self-Help Independent Study (SHIS) Group or The Self-Help Class (SHC) Group
n=77

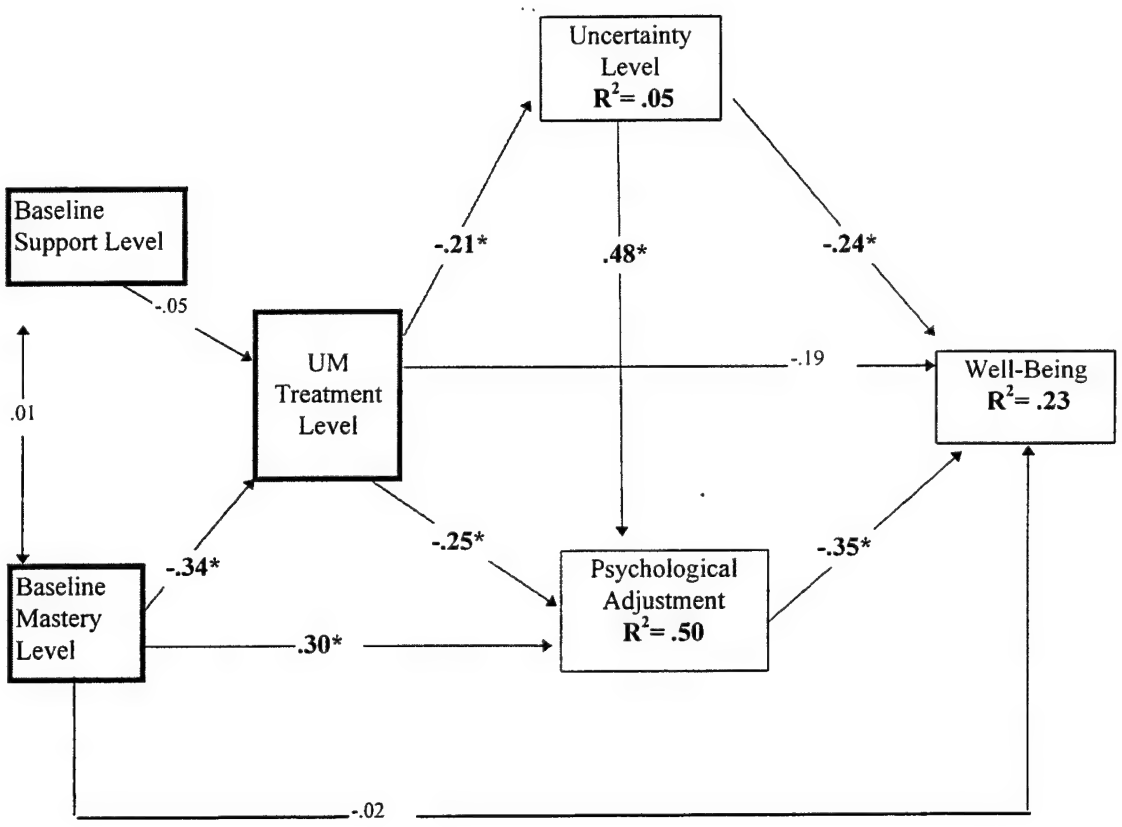
For this treatment group, the SHIS and SHC, 17 pertinent hypotheses were tested. Findings are presented in each hypothesis section.

Hypothesis 1. *The initial level of personal characteristics, age and education, may affect subjects' participation fully in the SHIP interventions.* Neither age nor education level had any statistically significant direct effect on patients' level of participation in the SHIS or SHC treatment.

Hypothesis 2. *Medical characteristics of therapy-related, as well as disease-related,, status may affect subjects' participation fully in the SHIP interventions.* Medical characteristics did not have a statistically significant direct effect on patients' level of participation in the SHIS or SHC treatment.

Hypothesis 3. *Participants' initial level of personal characteristics moderates the effects of SHIP interventions on proximal outcomes.* The interaction between personal characteristics (age,

Figure 4.8 Significant Findings of Relationships Among Conditioning Factors, Levels of UM Treatment, Proximal Outcomes, and Distal Outcome.



Independent Chi Square $_{(df15)}$ = 68.90, Model Chi Square $_{(df4)}$ = 4.59 , CFI =.98

education) and SHIS or SHC treatment did not have a statistically significant effect on changes in the level of 'enabling skills' or 'self-help'.

Hypothesis 4. *Participants' initial level of medical characteristics of therapy-related and disease-related status moderates the effect of SHIP interventions on proximal outcomes.* The interaction between medical characteristics and SHIS or SHC treatment did not have a statistically significant effect on changes in the level of 'enabling skills' or 'self-help'.

Hypothesis 5. *Participants' initial level of mastery moderates the affect of SHIP interventions on proximal outcomes.* The interaction between baseline mastery level and SHIS or SHC treatment did not have a statistically significant effect on changes in the level of 'enabling skills' or 'self-help'.

Hypothesis 6. *Participants' initial level of social support moderates the effect of SHIP interventions on proximal outcomes.* The interaction between baseline support level and SHIS or SHC treatment did not have a statistically significant effect on changes in the level of 'enabling skills' or 'self-help'.

Hypothesis 7. *Participants' personal characteristics directly affect the rate of change in well-being.* Personal characteristics (age, education) did not have a statistically significant direct effect on change in the level of 'well-being'.

Hypothesis 8. *Participants' medical characteristics directly affect the rate of change in 'well-being'.* Medical characteristics did not have a statistically significant direct effect on change in the level of 'well-being'.

Hypothesis 9. *Participants' initial level of mastery directly affects rate of change in 'well-being'.* Initial level of mastery had a no statistically significant direct effect on change in 'well-being'.

Hypothesis 10. *Participants' personal characteristics moderate the effect of SHIP interventions on distal outcome.* The interaction between personal characteristics and SHIS or SHC treatment did not have a statistically significant effect on change in the level of 'well-being'.

Hypothesis 11. *Participants' medical characteristics moderate the effect of SHIP interventions on distal outcome*. The interaction between medical characteristics and SHIS or SHC treatment did not have a statistically significant effect on change in the level of 'well-being'.

Hypothesis 12. *Participants' initial level of mastery moderates the effect of SHIP interventions on distal outcome.* The interaction between baseline mastery level and SHIS or SHC treatment did not have a statistically significant effect on change in the level of 'well-being'..

Hypothesis 13. *Those being in either the Self-Help Independent Study (SHIS) or Self-Help Class (SHC) will experience a change toward better 'enabling skills' (positive change pattern*). At group level, subjects in the SHIS or SHC groups had a slight gain rate in all the study's specified enabling skills': 'belief in self' (.63), 'cognitive reframing' (.45), and 'problem solving' (.01). Change in 'cognitive reframing skills' revealed a **statistically significant difference** from the control group (t=2.97, df=1, p=.09).

Individual parameters (intercept and slope) were used to test for the SHIS or SHC treatment effects on 'belief-in-self', 'cognitve reframing', and 'problem solving' using structural equation modeling. Treatment strength of SHIS or SHC **had a statistically significant** direct effect on change effect in 'cognitive reframing' (β=.29, $p<.10$).

Hypothesis 14. *Those being in either the Self-Help Independent Study (SHIS) or Self-Help Class (SHC) will experience a change toward more 'self-help' (positive change pattern).* At group level, subjects in the SHIS or SHC groups also had a large gain change rate in self-help (2.39). However, treatment strength of SHIS or SHC did not have a statistically significant direct effect on change effect in 'self-help'. Table 4.24 details the findings related to SHIS or SHC treatment affects on proximal outcomes.

Hypothesis 15. *Those subjects being in Uncertainty Management (UM) experienced change toward less 'uncertainty' (negative change pattern) over time.* This hypothesis was not applicable for GROUP C.

Hypothesis 16. *Those being in Uncertainty Management (UM) experienced change toward better 'psychological adjustment', or less negative affect (negative change pattern) over time.* This hypothesis was not applicable for GROUP C.

Hypothesis 17. *Those in the combined interventions of UM and SHIS or UM and SHC will experience a change toward less negative affect (negative change pattern), less uncertainty (negative pattern of change), more self-help (positive change pattern), and better enabling skills (positive change pattern) over time.* This hypothesis was not applicable for GROUP C.

Table 4.24 Summary of Group Level Change in Proximal Outcomes for **Group C** and the **Control Group**.

	Group 'C' SHIS or SHC (n=77)	**Group 6 NLC or Control** (n=54)
Changes in Enabling Skills		
Group Mean on **Belief-in-Self**	.63 SD 6.54	.49 SD 4.79
Negative Change Pattern	45.45% (n=35)	44.44% (n=24)
Positive Change Pattern	54.55 % (n=42)	55.56% (n=30)
Group Mean on **Cognitive Reframing** (t=2.97, df=1, p=.09)	**.45*** SD 4.38	-.99 SD 5.11
Negative Change Pattern	48.05% (n=37)	55.56% (n=30)
Positive Change Pattern	51.95% (n=40)	44.44% (n=24)
Group Mean on **Problem Solving**	.01 SD 4.69	-.76 SD 5.09
Negative Change Pattern	44.16% (n=34)	51.85% (n=28)
Positive Change Pattern	55.84% (n=43)	48.15% (n=26)
Change in Self-Help		
Group Mean	Mean 2.39 SD 7.04	Mean .60 SD 5.29)
Negative Change Pattern	33.77% (n= 26)	40.74% (n= 22)
Positive Change Pattern	66.23% (n=51)	59.26% (n=32)

Hypothesis 18. *Those subjects being in any SHIP intervention component will experience change (b) toward improved 'well-being'* . At group level, subjects in the SHIS or SHC group had a change rate of -.37 for 'well-being', as compared to a change rate of -1.35 in the control group. Table 4.25 shows that there were slightly more subjects with a positive change pattern in 'well-being' than negative change pattern (52.63% vs. 47.37%). There was an

equal number of subjects improved as not improved in the 'well-being' level of the control group. Statistically, there was **no statistically significant difference** between the treatment group and the control group.

The effect of SHIS or SHC treatment on 'well-being' was modeled with individuals' parameters (intercept and slope). Treatment strength of SHIS or SHC **did not have a statistically significant** direct effect on change in 'well-being'.

Table 4.25 Summary of Change in Well-Being for GROUP C and Control Group.

Change in Well-Being	**GROUP 'C' SHIS or SHC** (n=77)	**GROUP 4 NLC or Control** (n=54)
	Mean -.37 SD 8.47	Mean -1.35 SD 6.57
Negative Change Pattern	47.37% (n= 36)	50.00% (n= 27)
Positive Change Pattern	52.63% (n=40)	50.00% (n=27)

Hypothesis 19. *A change over time in enabling skills will lead to a change in 'well-being' over time.*

Change in 'belief-in-self' led to change in 'well-being' ($\beta = .19$, $p<.10$). The more change in 'cognitive reframing' also led to the more change in 'well-being' ($\beta = .28$, $p<.10$). However, more change in 'problem solving' led to a decline in 'well-being' ($\beta = -.27$, $p<.10$). Among 'enabling skills', the process of change was that change in 'belief-in-self' led to positive change in 'cognitive reframing' ($\beta = .40$, $p<.10$) which in-turn affected change in 'problem solving' ($\beta = .56$, $p<.10$).

Hypothesis 20. *A change over time in self-help will lead to a change in 'well-being' over time.* Change in 'self-help' leads directly to change in 'well-being'. That relationship was statistically significant ($\beta = .35$, $p<.10$).

Hypothesis 21. *A change over time in uncertainty management will lead to a change in 'well-being' over time.* This hypothesis was not pertinent to GROUP 'C'.

Hypothesis 22. *A change over time in psychological adjustment will lead to a change in 'well-being' over time.* This hypothesis was not pertinent to GROUP 'C'.

IN SUMMARY, at group level subjects who participated in the SHIS or SHC group had: 1) small to moderate gains in 'enabling skills' of 'belief-in-self' (.63), 'cognitive reframing' (.45), and 'problem solving' (.01). These subjects also had a large gain in 'self-help" (2.39). For 'well-being', subjects in the SHIS or SHC group had a small decline (-.37); whereas, subjects in the control group declined more rapidly (-1.35) over the one year period. However, the differences were **not statistically significant** when compared to the natural learning condition/control group.

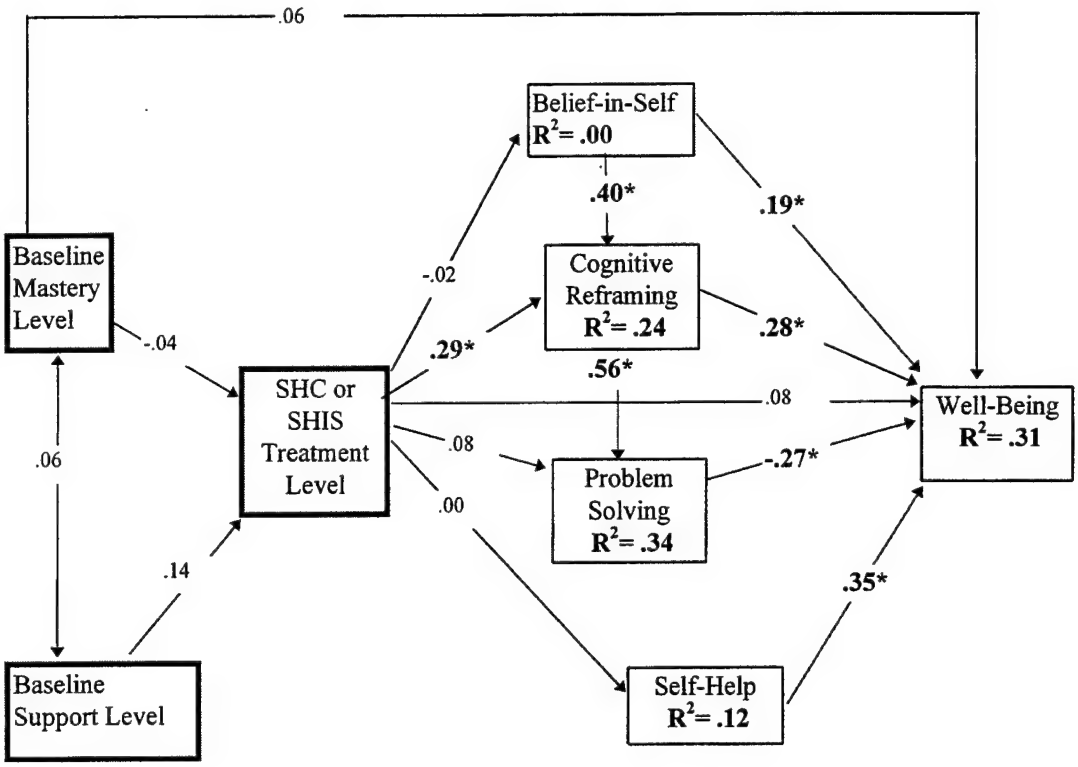
Relationships among conditioning factors, levels of SHIS or SHC treatments, proximal outcomes, and distal outcome are illustrated in Figure 4.9. Those findings are as follows:

1. The SHIS or SHC treatment influenced change in 'cognitive reframing' ($\beta = .29$, $p<.10$),
2. Change in 'belief-in-self' led to change in 'cognitive reframing' ($\beta = .40$, $p<.10$),

3. Change in 'cognitive reframing' led to change in 'problem solving' skills ($\beta = .56$, $p<.10$),
4. Increased change in 'belief-in-self' led to increased change in 'well-being' ($\beta = .19$, $p<.10$),
5. Increased change in 'cognitve reframing' led to increased change in 'well-being' ($\beta = .28$, $p<.10$),
6. Increased change in 'problem solving' led to the less change in 'well-being' ($\beta = -.27$, $p<.10$), and
7. Change in 'self-help' level had a statistically significant direct effect on change in 'well-being' ($\beta = .35$, $p<.10$).

As a whole, the treatment model of GROUP 'C' accounted for 31% of variance in change of 'well-being' with a good fit index of (CFI=.80).

Figure 4.9 Significant Findings of Relationships Among Conditioning Factors, Levels of SHIS or SHC Treatments, Proximal Outcomes, and Distal Outcome.



Independent Chi Square $_{(df28)}$ =116.75, Model Chi Square $_{(df12)}$ =29.35, CFI = .80

SUMMARY

The "typical" patient in this study is a white female in her middle age (55.5 years, ± 12), married, either employed full-time, or a full-time student or retired, with at least some college education, and a family income of approximately $1,500 per month. Medically, the 'typical' subject had stage I breast cancer, and experienced on average less than one other chronic illness besides breast cancer. The 'typical' subject also had moderate to high belief-in-herself as being capable of influencing her situation, while perceiving moderate tangible and intangible support from others.

On average, subjects in the Self-Help Independent Study (SHIS) received 45.75% of the treatment (SD 21.14 %). Subjects in the Self-Help Class received 53.95% of the intended treatment (SD 22.38%). Subjects in the Uncertainty Management Group received 45.23% of the intended treatment (SD 24.05). Subjects assigned to the combined SHC/UM group received 44.01% of the intended treatment (SD 16.97). Subjects in the SHIS/UM group received 50.85% of the intended intervention (SD 20.14).

One objective of this study was to determine which components of SHIP interventions and which activities in those identified components were most beneficial in promoting perceived 'well-being' in women receiving adjuvant therapy for breast cancer.

Which components were most beneficial in promoting perceived 'well-being'? The answers to this objective were answered at two levels: combined level (GROUP A, B, and C) and original SHIP's treatment level (SHIS, SHC, UM, SHIS/UM, and

SHC/UM). At the combined level treatments with the educational component alone (GROUP C) explained 31% of variance in change of 'well-being'. In treatment focused on the psychological aspects alone (GROUP B) accounted for 23% of variance in 'well-being'. Whereas, treatments using both educational and psychological aspects (GROUP A) explained the most variance in 'well-being' (46%). At SHIP's original treatment level, the two highest effective groups were SHIS (Group 5) and SHIS/UM (Group 2). The effect of the SHIS treatment accounted for 44% of variance in the change of 'well-being' with the model fit index of .95. The effect of the SHIS/UM treatment accounted for 49% of variance in the change of 'well-being', with the model fit index of 1.00. The effect of UM treatment accounted for 23 % of variance in change of 'well-being' with the model fit index of .98. The two lowest effective components were the SHC (Group 4) and SHC/UM (Group 1). There were no direct or indirect relationships among the SHC or SHC/UM treatments, proximal outcomes, and distal outcome (Table 4.26). The fit indexes were poor for both SHC (CFI =.38) and SHC/UM (CFI =.35) groups.

Which activities in the SHIP's components were most beneficial in promoting perceived 'well-being'? Among activities in lessons or classes offered to participants of the SHIS and SHC related treatment groups, the second and fourth lessons/classes were identified as most helpful to participants. Whereas, the fifth and sixth lessons/classes were identified as least helpful.

Table 4.26 The Effects of Treatment on Change in Well-Being by Treatment Groups

Treatment Groups	**Direct Effect** from Treatment to Well-Being	**Indirect Effect** from Treatment to Well-Being	**Comparative Fit Index**	**Variance Accounted** in Change in Well-Being by Treatment
Group 1 SHC/UM n=37	No	No	.35	38%
Group 2 SHIS/UM n=23	No	Yes	1.00	49%
Group 3 UM n=60	No	Yes	.98	23%
Group 4 SHC n=50	No	No	.38	34%
Group 5 SHIS n=27	Yes	No	.95	44%

Notes: SHIS = Self-Help Independent Study
SHC = Self-Help Class
UM = Uncertainty Management

At combined group level, change patterns in proximal outcomes were mixed. Change rate varied from large (i.e. -3.09 change rate in uncertainty) to small (.01 change rate in problem solving). Of all outcomes, larger change rates were found in the categories of self-help and uncertainty. The self-help and uncertainty change rates were consistent across all treatment groups. However, only change in 'cognitive reframing' **was statistically significant** in difference from the Natural Learning Condition (NLC) group/ control group (Table 4.27).

Table 4.27 Group Level Change Rate in Outcomes by **GROUPS (A, B, C)**

Change in:	**GROUP 'A'** SHIS/UM or SHC/UM n=60	**GROUP 'B'** UM n=60	**GROUP 'C'** SHIS or SHC n=77	**GROUP 6** Control Group or NLC n=54
Enabling Skills				
Belief in Self	.05	n/a	.63	.49
Cognitive Reframing	.16	n/a	**.45****	-.99
Problem Solving	.28	n/a	.01	-.76
Self-Help	1.50	n/a	2.39	.60
Uncertainty	-1.28	-3.09	n/a	-1.66
Psychological Adjustment	-.06	-.06	n/a	-.01
Well-Being	.19	-1.35	-.37	-1.35

Notes: SHIS = Self-Help Independent Study
SHC = Self-Help Class
UM = Uncertainty Management
NLC = Natural Learning Condition or Control Group
n/a = Not Applicable
** Statistically Significant ($p<.05$) Different from Control Group

Another objective of this study was to test the processes by which SHIP interventions affected the distal outcome 'well-being'. Testing the processes by which SHIP interventions affected the distal outcome 'well-being' was through answering the proposed hypotheses and model testing, using structural equation wherein variables of interest are tested simultaneously. In sum, treatments focused on educational aspects

which affected change in 'well-being' by way of 'cognitive reframing'. Treatment focused on psychological aspects affected change in 'well-being' through 'uncertainty' and 'psychological adjustment'. Treatments using both educational and psychological components affected change in 'well-being' via 'belief-in-self'.

Lastly, 10 out of 22 proposed hypotheses were supported. They are as follows:

1. No direct or moderating effect by age or education level was found; hypotheses #1, #3, #7, and #10 were not supported. Similarly, medical characteristics did not have direct or moderating effects; hypotheses #2, #4, #8, and #11 were not supported.
2. Baseline support level did not moderate the effect of treatment on proximal outcomes; hypothesis #6 was not supported.
3. Hypotheses #5 and #12 were not supported. Baseline mastery level did not moderate the effect of treatment on change of proximal outcomes or distal outcome. That is, the interaction between baseline mastery level and treatment level did not explain adequately the (5%) variance in the proximal outcomes. However, baseline mastery level had a negative direct effect (- .34) on treatment and psychological adjustment
4. (. 30) in the Uncertainty Management group (GROUP 'B'). This means that women who had a lower level of mastery at entry used or participated more in the UM treatment, and thus expressed better 'psychological adjustment'.
5. Hypothesis #9 was only supported in treatment groups SHIS/UM and SHC/UM.

6. Baseline mastery level also had negative direct effect (- .25) on change in 'well-being' in GROUP 'A'. This means that the women who had a high baseline mastery level did not do as well, in terms of change in 'well-being' as the women who had a lower baseline mastery level with or without SHIS/UM or SHC/UM treatments.
7. Hypothesis #13 was supported. There were direct treatment effects on two of three 'enabling skills'. First, change in 'belief-in-self' was influenced by treatment level of SHIS/UM or SHC/UM (β=.27, $p<.10$). Second, change in 'cognitive reframing' was influenced by treatment level of SHIS or SHC (β=.29, $p<.10$).
8. Hypothesis #14 was not supported. There was no direct effect of treatment on self-help.
9. Hypothesis #15 was supported. There was a direct UM treatment effect on change in 'uncertainty' (β=-.21, $p<.10$).
10. Hypothesis #16 was supported. There was a direct effect of UM treatment on change in 'psychological adjustment'(β=-.25, $p<.10$).
11. Hypothesis #17 was partially supported in the SHIS/UM and SHC/UM treatment groups. The effect of treatment was differential, depending upon the strength of treatment taken. The SHIS/UM or SHC/UM treatment had a direct positive change on 'belief-in-self' (β=.27, $p<.10$).
12. Hypothesis #18 was not supported. None of the treatment components (SHIS, SHC, UM, SHIS/UM, and SHC/UM) had a direct effect on change in 'well-being'.

13. Hypothesis #19 was partially supported. Change in 'belief-in-self' led to change in 'well-being' for GROUP 'A' (β=.25, $p<.10$) and GROUP 'C' (β=.19, $p<.10$). Change in 'cognitive reframing' led to change in 'well-being' for GROUP 'A' (β=.21, $p<.10$) and GROUP 'C' (β=.28, $p<.10$). However, increased change in 'problem solving' led to a decline in 'well-being' instead for GROUP 'C' (β=-.27, $p<.10$).
14. Hypothesis #20 was supported only in GROUP 'C'. Change in 'self-help' led to change in 'well-being', but was only supported in the SHIS or SHC group (β=.35, $p<.10$).
15. Hypothesis #21 was supported. Change in 'uncertainty' led to change in 'well-being' (β=-.24, $p<.10$) for GROUP 'B'.
16. Hypothesis #22 was supported. Change in 'psychological adjustment' led to change in 'well-being' (β=-.35, $p<.10$) for GROUP 'B'.

The last objective of this study was to profile which individuals were most likely to benefit from specific components of SHIP interventions. Participants were profiled according to several factors: personal characteristics, medical characteristics, initial mastery level, and initial level of social support level. Among these, baseline mastery level and age were statistically significant predictors. Those who showed a positive change pattern in 'self-help' in the SHIS treatment group were younger. However, the interaction effect between age and SHIS treatment did not have a statistically significant effect on change in outcomes. In the UM treatment group, those who had a decline in

'negative affect' (42.65%, n=29) also had a statistically significant lower baseline mastery level (63.60) compared to the non-improved group (79.7).

Interpretations of these findings and implications for nursing practice are presented in the next chapter, along with recommendations for further analysis and study.

CHAPTER V

INTERPRETATION, RECOMMENDATIONS, AND IMPLICATIONS

In this chapter, findings of the study are summarized and discussed in relation to the theoretical framework which guided the study and the proposed hypotheses. In addition, recommendations for future investigations and implications of this study are presented.

INTERPRETATION

The primary purpose of this study was to further develop treatment theory in order to better understand and explain the dynamics of the SHIP interventions . This study attempted to 1) determine which components of SHIP interventions and which activities in those identified components were most beneficial in promoting perceived 'well-being' in women receiving adjuvant therapy for breast cancer; 2) profile which individuals were most likely to benefit from specific components of SHIP interventions, and 3) test the processes by which the SHIP interventions affected the outcomes. Discussion of these aims is integrated within each SHIP treatment component.

Which SHIP Components Resulted in Significant Improvement in Perceived Well-Being?

Which components (educational, psychological, or both) affected change in 'well-being' the most. Looking at the combined level, treatments used both educational and psychological aspects (GROUP A), was most effective (explained 46% of variance,

CFI=1.00). The second most effective component was psychological; the UM group accounted for 23% of variance in change of 'well-being', and had a high fit index of .98.

Which treatment was most effective in improving change of 'well-being'? The two highest effective groups were SHIS (Group 5) and SHIS/UM (Group 2). The effect of the SHIS treatment accounted for 44% of variance in the change of 'well-being', and had a model fit index of .95. The effect of the SHIS/UM treatment accounted for 49% of variance in the change of 'well-being' , and had a model fit index of 1.00. The effect of UM treatment accounted for 23 % of variance in change of 'well-being', and had a model fit index of .98. The two lowest effective components were the SHC (Group 4) and SHC/UM (Group 1).

As related to change rate and change pattern at original SHIP's treatment group level (SHIS, SHC, UM, SHIS/UM, and SHC/UM), the mean level of change in outcomes were mixed. When compared to natural learning condition/control group, only three treatment groups were different to a statistically significant degree. Change in 'cognitive reframing' over the 12 month period was significant in the SHC group. Change in 'problem solving' over a 12 month period was significant in the UM group. Change in 'self-help' over a 12 month period was significant in the SHC and SHC/UM groups. The remaining changes in outcomes were not significantly different from the control group. However, individuals' change rates varied widely within each treatment group. A large number of outliers relative to the small sample size in the treatment group may explain

the unexpected change pattern in each treatment group. When the sample size was improved by way of combining treatment groups with similar treatment specificity (educational, psychological, or both), change pattern in outcomes were all in the expected direction, except for a small decline in 'well-being' for GROUP C (-.37).

In the following sections, the effects of each treatment are discussed in more detail. The order of presentation is from the strongest to lowest effective group.

Perceived Well-Being is Strongest In the Self-Help Independent Study (SHIS) Plus Uncertainty Management (UM) - Group 2: The combined SHIS/UM treatment aims to enhance patients' problem solving skills, cognitive reframing skills, self-belief skills, and self-help skills. That combined treatment also aims to assist clients in dealing with uncertainty, as well as reframing uncertainty in a different and positive perspective.

On average, subjects participated in 50.85% (SD 20.14%) of the SHIS/UM treatment. Quantification of treatment strength for this group was determined by a total score derived from: the proportion of lessons completed, helpfulness level of the lessons, number of contacts with client-case manager, and satisfaction with uncertainty management treatment.

At group level, subjects in the SHIS/UM group revealed mixed change patterns and moderate change rates. Four out of seven change patterns were in the opposite direction expected. For example, subjects had negative change in 'belief-in-self' (-1.35),

'problem solving' (-.01), 'self-help' (-.90), and 'well-being' (-.01) Although the changes in 'problem solving' and 'well-being' were negative, the magnitude was close to zero. As discussed earlier, negative change patterns ('belief in self' and 'self-help') were partly due to large outliers relative to the sample size. Six out of 23 subjects (26%) in the SHIS/UM group had an extreme drop in 'self-help', while other subjects experienced slow improvement in 'self-help'. Thus, the change patterns at group level may be unstable due to small sample size (n=23). Overall, the women in this sample varied considerably in their initial status, as well as their change trajectory. In a preliminary analysis, a clear pattern emerged. Those with lowest initial status made the most progress. On the other hand, those with high initial status made the least progress. Preliminary findings are provided in Appendix F.

What are the processes by which the SHIS/UM treatment affected the outcome?

To examine the group at a different level, individuals' parameters (intercepts and slope) were used to model: 1) the effect of the SHIS/UM treatment on outcomes, and 2) the process by which the SHIS/UM treatment affected the distal outcome of 'well-being'. The SHIS/UM treatment affected change in 'cognitive reframing' (β=.36) indirectly through change in 'belief-in-self' (β=.41). The direct effect from SHIS/UM treatment on change in 'cognitive reframing' was negligible (β=.09). Gaining in 'cognitive reframing' improved 'well-being' (β=.46). Although the effect of SHIS/UM on change in 'uncertainty' level was not at a statistically significant level (β=.06), change in

'uncertainty' directly affected change in 'well-being' (β=-.35). The less uncertainty the subjects moved toward, the higher the level of well-being they perceived.

The significant negative relationship (r= -.55, $p<05$) between days from diagnosis to SHIS/UM treatment versus change in 'problem solving' may account for the lack of direct effect of SHIS/UM treatment on change in 'problem solving'. The longer the women had been living with breast cancer, the less change they had in learning 'problem solving'. These women may have already achieved their 'problem solving' skills, and having learned more about problem solving apparently did not contribute to a significantly detectable change rate. On the other hand, women who had less time pass since their cancer diagnosis , to the moment of commencement with SHIS/UM treatment, also changed more in 'problem solving' skills. Facing a new adversity, the newly diagnosed women would have more concerns and problems related to breast cancer therapies than those diagnosed earlier (Weisman & Worden, 1976-77).

What is the profile of the women who benefited from the SHIS/UM treatment? Factors such as Socio-Economic Status (SES), age, education level, severity of illness, and baseline mastery level were not significant moderators in self-care as suggested by Albrecht & Nelson (1993), or psychological function as suggested by many (Andersen, 1993; Dunkel-Schetter, 1984; and Funch & Mettlin, 1982). Findings of this study support others' (Roberts et al., 1994; Sidani & Braden, 1992) findings, namely baseline support level did not account for variance in 'well-being'. On the contrary, both baseline

levels of mastery and support influenced the subjects' participation in the SHIS/UM treatment. Subjects with lower mastery level participated more in SHIS/UM. Similarly, subjects with lower support level, at entry into the SHIS/UM treatment, participated more. The SHIS/UM appeared to work better for subjects with lower resources: mastery and support.

Perceived Well-Being from the Self-Help Independent Study (SHIS)

Group 5: On average, subjects in this group received approximately 45.75% (SD 21.14%) of the SHIS treatment. Treatment strength was determined by proportion of lessons completed and the level of helpfulness of the activities/lessons as perceived by the participants. The activities in the SHIS were structured to enhance patients' problem solving skills, cognitive reframing skills, belief-in-self skills, and breast cancer information. As a result of SHIS treatment, the subjects should be more able to: 1) pose their situation in a different light, or interpret their situation from a different perspective, 2) consider alternatives, and 3) overcome difficulties.

At group level, subjects in the SHIS treatment group (n=37) exhibited expected change patterns in: 'belief-in-self' (.26), 'cognitive reframing' (.18), 'self-help' (1.22), 'uncertainty' (-1.39), and 'psychological adjustment' (-.02). But, they also showed unexpected change patterns in: 'problem solving' (-.38) and 'well-being' (-2.51).

What is the profile of the women who benefited from the SHIS? The women who showed positive change pattern in 'self-help' tended to be younger than the 'non-

improved' group by 10 years (t=4.61, p=.05). This finding corroborates Brown's (1992) report in which the author inferred that educational programs, specifically knowledge related, were more effective with younger patients. Additionally, women with higher support level at entry, participated more in self-study. Having support, i.e. emotionally or instrumentally, encouraged the women to do more self-study. Further examination shows that those with lowest initial status (in any outcomes) made the most progress. On the other hand, those with high initial status made the least progress. Thus, it would be more cost efficient if the treatment were offered to those with low initial status. Preliminary findings are provided in Appendix F.

How effective was the SHIS? Completing the lessons' materials, and rating specific lessons as helpful resulted in change of 'cognitive reframing' (β=.37). Reading materials related to: how to do and use relaxation, how to use available resources, how to use coping strategies that work, and how to become knowledgeable about breast cancer influenced a positive change for 'cognitive reframing'. It is possible that the education level of younger patients contributes to the potency of the self-study lessons. That is, subjects with higher education level can extract more from the written lessons, as well as be more able to put what have learned into practice.

It is important to note that the fifth class which deals with loss, grief, and relaxation was rated as least helpful. The fifth class also was rated as least helpful in other groups (SHIS/UM, SHC/UM, and SHC). One explanation for this perception could

be that most subjects were within four months of having been diagnosed with breast cancer, as well as being in the early stage of breast cancer. Another explanation is that the subjects were uncomfortable, in general, with the topic of loss and grief.

What are the processes by which the SHIS treatment affected the outcome? Treatment framework of this study addresses issues such as what intervening and conditioning variables could moderate the relationship between treatment and outcome. According to the treatment framework of this study, conditioning variables such as age, severity of illness, and baseline mastery level can moderate the affect of SHIS treatment on immediate outcomes of 'enabling skills' and 'self-help' prior to its effects on the 'well -being' distal outcome. Findings indicate that the effect of SHIS treatment on change in 'well-being' was mediated first through change in 'cognitive reframing' then change in 'problem solving'. However, change in 'problem solving' led to less change in 'well-being'. For those patients who had low 'problem solving' skills to start with, there may have been a feeling of being overwhelmed or distressed with the new way of facing and solving problems. This finding is inconsistent with the Self-Help Model. However, there was a significant direct effect resulting from change in 'self-help' upon change in 'well-being' (β=.65).

In summary, treatment theory which guided this secondary analysis of the SHIP study specified that 'enabling skills', 'self-help', 'uncertainty', and 'psychological adjustment' mediate the effect of SHIP treatment components on change in 'well-being'.

Of all mediators specified, four ('belief-in-self', 'cognitive reframing', 'uncertainty, and 'psychological adjustment') indeed mediated the treatment effects on distal outcome of 'well-being'. Other findings indicated that there were significant relationships among these mediators which need further 'un-packaging'. Specifically, what is the process of change among mediators? Change in 'cognitive reframing' seems to be most salient. But, which of the three 'enabling skills' occurs first? Does change in 'enabling skills' occur prior to change in 'self-help' or vice-versa, or do they occur concurrently? Although one aim of this study was to 'un-pack' the 'black box', this study's 'black box' contains yet smaller 'black boxes', and those smaller 'black boxes' still need 'un-packaging'.

The second aspect of treatment theory was specification of which conditioning variables would moderate the relationships between the treatment components and outcomes. Among specified conditioning variables, only age, baseline mastery level, and baseline support level were significant contextual factors in influencing the transformational relationship between treatment components and outcomes. For example, the SHIS treatment was more effective for younger women, and the UM treatment was more effective for women with lower baseline mastery level or less effective for those women having high mastery level at time of entry.

The last aspect of the treatment theory was to consider the relative effect of treatment strength on outcomes. Although the strengths of the various SHIP components

were quantified, the quantification method employed was far from comprehensive. Many other domains, which were not examined by this study but can further be secondarily analyzed, may bolster the findings.

Perceived Well-Being In the Uncertainty Management (UM) Group 3:

Uncertainty Management (UM) treatment is the individualized intervention offered over the telephone by trained nurse-client managers following a standardized protocol to provide counseling intended to assist participants in managing their perceived uncertainty. The UM intervention is based on the Self-Help Model, and aims to assist clients deal with uncertainty, and to reframe uncertainty in a positive perspective of challenge rather than threat.

On average, subjects in this group participated in 45.23% (SD 24.05%) of the intended treatment. Treatment strength was determined by: 1) the number of telephone contacts between the nurse client mangers, and 2) the subjects' perceived satisfaction level.

There was a direct negative effect from baseline mastery level on the levels of the UM treatment taken by participants (β= -.34). The greater the mastery level prior to entry into UM treatment, the less the participation (as measured by UM treatment level) by the subjects. However, even though women having high levels of mastery at time of entry participated less in the UM treatment, they were satisfied with treatment they had received. Women with higher mastery may have adequate personal resources to handle

their situation with minimal help. Once they receive enough 'start up' help, they can carry on. Thus, women with high baseline mastery level may have benefited more with less UM intervention. Whereas, women with low baseline mastery level would benefit more from a full strength of UM intervention. These hypotheses can be investigated by further analyzing the collected SHIP data.

At group level, all change patterns for the UM treatment group were in the directions expected: 'belief-in-self' (2.12), 'cognitive reframing' (.39), 'problem solving' (1.27), 'self-help' (1.37), 'uncertainty' (-3.09), 'psychological adjustment' (-.06), and 'well-being' (.17). The steepest change rates were revealed by 'belief in-self' level and 'uncertainty' level.

What are the processes by which the UM treatment affected the outcome? The level of UM treatment directly affected a change in 'psychological adjustment' (β=-.25) and 'uncertainty' level (β=-.21). Both changes in 'uncertainty' level (β=-.24) and 'psychological adjustment' (β=-.35) directly influenced change in 'well-being'. Additionally, less 'uncertainty' led to better 'psychological adjustment' as measured by less 'negative affect' (β= .48). As a whole, the model for UM treatment explained 23% of the variance in perceived 'well-being'. An effect size of 23% is small, however small effect size is expected for several reasons. First, effect size is dependent upon number of variables in the model. The more 'variables' or 'parameters' added to the model, the more explanation power or effect size is expected from the model. In the UM treatment

model, 23 % of variance was accounted for by five variables with 11 parameters ; the fit index was .98. Thus, the UM treatment model is well specified. A second explanation for small effect size is related to changes in 'global' outcomes. A 'global' dependent variable such as 'well-being' is difficult to measure directly or indirectly. 'Global' outcomes are multidimensional, thus are usually influenced by multitudinous factors (Abelson, 1995; Prentice & Miller, 1992). A third explanation for small effect size found in change of 'well-being' is 'asymmetry'. The UM treatment's main aim was to assist clients deal with uncertainty and reframe uncertainty in a positive perspective of challenge rather than threat. The more certain and positive they became, the less negative affect they experienced. Indeed, that was the case; both changes in 'uncertainty' and 'psychological adjustment' were significant. Therefore, matching appropriate level of outcome measures to the level of treatment delivered is most critical in detecting treatment effectiveness (Wittmann, 1996).

Overall, the UM treatment is consistent with the Self-Help Model (Braden, 1990a; 1990b) and the Uncertainty in Illness Theory (Mishel, 1990a; Mishel, et al., 1991). Both theories hold that if a person feels less uncertain about the illness experience, then with a decrease in uncertainty and an increase in psychological adjustment, the persons' perceived overall well-being is maintained or enhanced.

What is the profile of the women who benefited from the UM treatment? Out of 68 women, 29 demonstrated the expected negative change pattern in 'psychological

adjustment'. These women also had much lower mastery level (63.6 versus 79.6 for high mastery subjects) at entry into the UM treatment (t=2.85, p=.07). Furthermore, the low mastery women also experienced a higher participation level in the UM treatment (t=3.97, p=.05). Similar to other findings (Mishel & Sorenson, 1991; Mishel et al., 1991), women with a higher level of uncertainty, but without skills to handle the uncertainty, are benefited from treatment such as the UM which aims to deliver needed individualized treatment as assessed by the nurse-client manager. Patients with high mastery level can handle distress and uncertainty more effectively, and may not need or benefit from psychosocial intervention (Edgar et al., 1992), such as the UM treatment. It is possible that women with high mastery level have resolved uncertainties for themselves in some way, and at a different rate than women with lower mastery level. It may be fruitful to further explore these relationships in order to better match treatment options to individuals. But contrary to various reports (Cassileth et al., 1984; Roberts et al., 1994; Vinokur et al., 1989), other personal characteristics and the social support level did not affect or moderate psychological adjustment level in this study.

Perceived Well-Being In the Self-Help Class (SHC) Plus Uncertainty Management (UM) Group 1: The combined SHC/UM treatment was similar to the combined SHIS/UM treatment, except that the lessons were delivered by trained teachers in a classroom setting. The SHC/UM aimed: to enhance patients' problem solving skills, cognitive reframing skills, belief-in-self skills, and self-help skills. It also aimed to

assist clients in dealing with uncertainty and reframing uncertainty in a different and positive perspective.

On average, subjects participated in 44.01% (SD 16.97%) of the SHC/UM treatment. Quantification of treatment strength for this group was by a total score derived from: proportion of lessons completed, helpfulness level of the lessons, number of contacts with client case manager, and satisfaction with uncertainty management treatment.

At group level, subjects in the SHC/UM group showed fairly consistent change patterns and fair change rates. All change patterns were in the expected directions, except for change in 'cognitive reframing'. The focus of SHC/UM was on improving 'self-help' and managing 'uncertainty'; it was expected that the subjects would improve in 'self-help' (2.99), and perceive less 'uncertainty' (-1.57).

What are the processes by which the SHC/UM treatment affected the outcome? There were detectable changes in 'belief-in-self' (β=.16), and 'cognitive reframing' (β=.22). However, these changes were not at a statistically significant level ($p<.10$). Change in 'belief-in-self' led to more change in 'cognitive reframing' (β=.41), which in-turn led to more change in 'problem solving' (β=.23). Both changes in 'belief-in-self' and 'problem solving' led to change in 'well-being'.

Another focus of SHC/UM was on helping subjects manage their uncertainty better. At group level, the subjects displayed -1.47 rate of change in the expected

direction. However, this change in 'uncertainty' did not mediate the effect of level of SHC/UM treatment on change in 'well-being'. Though the model for SHC/UM treatment explained 37% of variance in change of 'well-being', the model fit index was poor (CFI .34). Poor fit index indicates the model that the postulated relationship among variables is not plausible, thus the tenability of such relations is rejected (Byrne, 1994). Small effect size, on the other hand, can result from: manipulation of the treatment variable being minimal (Abelson, 1995; and Prentice & Miller, 1992), when written treatment protocol is not adhered to, or when the treatment is not taken as intended (i.e. 100%). A plausible explanation could be that the protocol was not adhered to. Despite intensive training and following the standardized assessment tool, the nurse-client managers providing the UM treatment might not have been consistent or sensitive in identifying individual subjects' concerns and needs. Having a standardized treatment protocol provides consistency in materials/interventions being delivered over time and among interveners. However, the consistency of how the materials/interventions are delivered is related to 'integrity'. 'Integrity' refers to the degree which treatment is delivered as intended (Sechrest et al. 1979; 1979). Even strong treatment, if allowed to depart from standardized protocol, may prove ineffective (Yeaton & Sechrest, 1981). Thus, the degree to which the treatment is consistently adhered to is critical, and may prove to be a more relevant indicator for indexing treatment strength than, for example, the education level of the intervener. This hypothesis can be further explored by auditing all the

recorded interactions between nurse-client managers and subjects. This auditing study can be accomplished in another secondary analysis study.

Besides these aforementioned factors, other situations such as teachers' varied personal characteristics, communications skills with subjects, and frequency and quality of previous experiences in caring for women with breast cancer may influence the affect of treatment on outcomes The interviewers' characteristics is a category which has been identified by many investigators as being a crucial factor in effectiveness of a particular treatment i.e. psychoeducational programs (Oberst, 1989).

Lastly, the treatment framework specified that conditioning variables such as age, severity of illness, and baseline mastery level can moderate the affect of SHC treatment on immediate outcomes of 'enabling skills' and 'self-help' prior to its effects on the 'well -being' distal outcome. Findings indicate that there was no direct relationship between the level of SHC treatment and proximal outcomes or distal outcome as proposed by the treatment framework of this study. However, there was a significant direct effect resulting from change in 'cognitive reframing' upon change in 'well-being'. It is possible that the level of SHC treatment affects some unmeasured variables which in-turn affect 'belief-in-self', 'cognitive reframing', 'problem solving', or 'self-help', followed by change in 'well-being'. For example, it is possible that reading about breast cancer, its treatment, and treatment effects will affect a change in knowledge level immediately. Whereas, 'belief-in-self' or 'problem solving' may require more time to

allow subjects to practice and apply what they learned. Moreover, only when the subject applied what was learned successfully could 'belief-in-self' take place. Thus, the 'black box' between treatment and outcomes still needs to be illuminated. This can be accomplished by further secondary analysis of collected data from the SHIP.

Perceived Well-Being from the Self-Help Class (SHC) - Group 4: On average, subjects in this group participated in 53.95% or 4.5 hours (SD 22.38 %) of the intended treatment. Treatment strength was determined by proportion of classes (total of 6) completed, in addition to the level of helpfulness of the activities/classes as perceived by the participants. Activities in the SHC were structured to enhance patients' problem solving skills, cognitive reframing skills, self-belief skills, and self-help skills.

At group level, all change patterns for the SHC treatment group were in the expected directions: 'belief-in-self' (.82), 'cognitive reframing' (.60) 'problem solving' (.21), 'self-help' (3.02), 'uncertainty' (-1.95), 'psychological adjustment' (-.05), and 'well-being' (.78). However, only change in 'self-help' ($t=4.39$, $p=.04$) and 'cognitive reframing' ($t=3.20$, $p=.08$) were significant when compared with change in the control group, as a result of the level of SHC treatment. Although, when individuals' parameters (intercept and slope) were used for testing treatment effect on both proximal and distal outcomes, neither direct nor indirect effect was found. It is concluded that taking roughly 50% of the SHC treatment helped the women in managing their care. Receiving information and discussing with teachers topics such as the nature, manifestations,

treatment for, and ways of dealing with breast cancer approximately 4.5 hours was not sufficient to bring about direct changes in the specified skills: 'belief-in-self', 'cognitive reframing', and 'problem solving'.

Over a one year period of time, the SHC treatment did not affect any of the specified proximal outcomes at a statistically significant level. However, there were detectable betas in change of 'cognitive reframing' (β=.17) and 'problem solving' (β=.21). A plausible explanation is that the effect of SHC treatment on proximal outcomes was more salient during the early follow-up period. This hypothesis can be further explored in another study in which data are collected more frequently (as guided by theory). Change in 'cognitive reframing' contributed to change in perceived 'well-being' for women participants in the SHC treatment group. Even though the level of treatment provided by the SHC was not statistically significant in affecting change in 'cognitive reframing' directly, it was affected in sufficient amount (β=.17) to mediate the effect of SHC treatment on change in 'well-being'. Additionally, change in 'problem solving' was affected by the SHC treatment at a sufficient level (β=.21), though not statistically significant level. Level of change in these theory identified mediating variables was possibly sufficient to mediate the change in 'well-being'. This hypothesis could be examined by further analyzing the SHIP data using structural equation modeling at combined group level.

Another alternative explanation is that being in class, interacting with others who were experiencing similar conditions, and sharing trials and tribulations may have helped subjects in clarifying their own situation; these interactions and sharing move the subjects to a higher level of 'well-being' (Hagopian, 1993; Hilton, 1988; Ireland, 1987; Kushner, 1982; Moch, 1990; 1995). This hypothesis can be further explored by examining the number of women participating in each class, as well as whether or not the class composition made a difference. Additional exploration of the relationships among 'self-help', 'cognitive reframing', and 'belief-in-self' is necessary for refinement of the SHIP interventions, in terms of treatment delivery intervals, or delivery of booster treatment.

Although speculated factors (age, education level, degree of illness, baseline support level, and baseline mastery level) did not seem to interact with the level of Self-Help Class to moderate changes in outcomes, other potentially moderating factors remain to be investigated. Alternative factors, including physical condition and cognitive processes of the attendants, may interfere with the subjects' ability to process and apply what was offered.

RECOMMENDATIONS

Although the SHIP study was well designed, it also had limitations: attrition, mono-method bias, and self-selection bias to name a few. Based on this critique and the findings, recommendations are to: 1) do more secondary analysis of the original SHIP study, and 2) do more studies.

More Secondary Analysis Studies

1. Re-examine intervenors' characteristics through further secondary data analysis of the SHIP study. Examine the role of those intervenors, as well as their individual characteristics and how those characteristics affect delivery of treatments and resultant outcomes.

2. Match the appropriate level of outcome measures to the intended intervention. For example, one component of SHIP interventions was related to education; thus, the more appropriate level of outcome measure would be 'change in knowledge level'. A symmetrical matching of outcome measures to intervention measure is necessary to detect treatment effects (Wittmann, 1996).

3. Re-model the treatment theory with more relevant variables which may explain the mediating process more fully. Rather than a two-steps process treatment to 'enabling skills and to the distal outcome of 'well-being', the mediating process might involve additional steps. In explaining the transformational relationships between treatment and outcome, one must also examine the contextual and mediating factors under which the conversion process occurs (Chen & Rossi, 1983; 1987; Cordray, 1989; Costner, 1989; Lipsey, 1993).

4. Further explore the number of women participating in each class, as well as whether or not the class composition moderates the treatment effects. Being in class, interacting with others who experienced similar conditions, and sharing trials and tribulations may

have helped subjects in clarifying their own situation; these interactions and sharing move the subjects to a higher level of 'well-being' (Hagopian, 1993; Hilton, 1988; Ireland, 1987; Kushner, 1982; Moch, 1990; 1995).

5. Explore 'personal characteristics' in more detail. Preliminary findings, using structural equation modeling' show that those with lowest initial status made the most progress. On the other hand, those with high initial status made the least progress. Secondary data analysis is needed to confirm this pattern. Treatments are most cost effective when they are given to or offered to those who benefit most.

More Studies

1. Replicate part of this study, using only the stronger components such as SHIS/UM in a more homogeneous sample; for example, recruit only newly diagnosed women (within six months of diagnosis). This strategy allows for: 1) a smaller number of treatment groups to be tested so there is a higher probability of recruiting more subjects (n=5 to 10 per parameter, Bentler, 1980, 1992) into each treatment group; and 2) keeping the sample homogeneous, which would allow probing of outcomes that are sensitive to change. The correlation between true change rate and initial status depends crucially on the choice of when to perform the baseline measure (Rogosa, 1995). For example, the change rate in 'problem solving' differed between women who were newly diagnosed versus women had been diagnosed many months ago in the SHIS/UM group. Six weeks of psychoeducational treatment may be more effective for women who have recently been

diagnosed with breast cancer. However, in order to sustain the treatment effect over time, it may be necessary to administer 'booster' lessons.

2. Replicate this study using a larger sample size. Larger sample size improves statistical power for simultaneously examining the complete model: direct effects, indirect effects, interaction effects among conditioning variables, interventions, proximal outcomes, and distal outcome. When using the structural equation modeling approach, per Bentler (1980, 1992) it is suggested that a ratio of five cases per estimated parameter as a minimum be used, and preferably 10 cases per estimated parameter. Inclusive model testing makes it possible to address complex research questions. For example, what is the mechanism by which psychoeducational interventions influence change in outcomes? Moreover, inclusive model testing will also strengthen treatment theory by addressing questions such as: 1) which other variables functioned as mediators in the change process? and 2) which conditioning variables influenced the interventions' effects on the outputs? These questions are integral to "treatment theory" (Lipsey, 1993) in order to optimize the interventions' effects.

3. Design, implement, and evaluate an alternative mode of delivery for the self-help course, i.e. by video tape or on-line interactive (computer). Given that the two most effective treatments of the SHIP were self-study related, it is reasonable to suggest that patients' choice is critical. The alternative modes of delivery suggested above are flexible, related to time, place, and pace. Participants can select the lessons that are most

relevant to them. For example, lessons two, three, and four of the SHC and SHIS were rated as most useful; whereas, lessons five and six were rated as least useful by most subjects. Patients can decide the amount of time they want to spend on the materials, and in their choice of environment.

4. Use alternative methods of measurement to capture the changes in outcomes. For example, measure functional status as measured by performing self-care, and returning to one's school/work/hobby. Another method of measurement can be the pencil-paper method, but responses will be from relatives or significant others. Using alternative methods reduces the potential testing affect that poses a threat to internal validity, as well as improves construct validity by reducing measurement errors.

5. Measure more frequently, especially during the treatment period, as well as during the follow-up period. In order to assess change, a minimum of three data was recommended by many (MacKinnon, 1996; McArdle & Hamagami, 1991, Nesselroad, 1991; Rogosa, 1995). Thus, to assess immediate change resulting from interventions, a minimum of three data points during the intervention period is needed. The more data points the better. Frequency of measurement should be guided by theory, as well as past research. Use of more data points 1) allows investigation of change during treatment; 2) increases the reliability of estimated individual regression; 3) allows closer examination of change trajectory (upward versus downward) during the follow-up period; and 4) permits examination of sustained effects, that is assessment of change during follow-up. In order

to examine change during treatment, a minimum of three data points during treatment is recommended. To ascertain the lasting effect of treatment, it is recommended that another three data points be added during post treatment. More data points allow exploration of timing of change as related to improvement or deterioration. Timing of changes enables determination of when to offer booster lessons. The frequency of measurements during short interventions (i.e. 2 weeks) must be balanced between the benefits (improvement of reliability, demonstrated change) and costs (test/retest effects, respondents' burden).

6. Replicate this study with modified treatment specificity, i.e. double the main ingredients. Finding from this study suggest that 'cognitive reframing' was the strongest ingredient among all three 'enabling skills'. Treatments can be strengthened by increasing the dose of main ingredients, and deleting the nonessential ingredients (Sechrest et al., 1979).

IMPLICATIONS

As indicated in the above recommendations, re-examination of this study and replication of part of this study are suggested, prior to applying the findings of this study to clinical practice. At treatment group level, change in 'cognitive reframing', 'problem solving', and 'self-help' were significantly different from the Natural Learning Condition (NLC)/Control group over the study's one year period The SHIS/UM, SHIS, and UM treatments accounted for a moderate amount of variance in changes to outcomes.

Considering the short treatment duration (six weeks) and moderate treatment strength (~ 50%) taken by the subjects, and the more than one year used to assess intervention effects, there were some surprisingly encouraging findings. At the individual level, treatment effects, sustained over the one year period, were changes in: 'belief in self' (from SHIS/UM treatment), 'cognitive reframing' (from SHIS treatment), 'uncertainty' (from UM treatment', and 'psychological adjustment' (from UM treatment). Hence, the implication is that SHIP interventions of SHIS/UM, SHIS, and UM, in general, are relatively effective in producing the desired changes. The SHIP interventions improved the women's skills in 'belief-in-self' and 'cognitive reframing'. The SHIP interventions also reduced the women's 'negative affect' level and 'uncertainty' level. Clinicians can use these findings to assist them in the care of women with breast cancer, but with the following precautions:

1. Psychoeducational interventions such as those offered by the SHIP, with components that have tightly focused 'specificity', may be more effective than non-specific interventions. For example, the SHC had a high 'cognitive' component as an active ingredient, which was designed to improve self-help, and resulted in significant change of 'self-help' level. Similarly, the UM treatment's active ingredient was 'psychological', and was designed to assist patients in managing uncertainties. Consequently, clinicians need to identify and apply the appropriate components to bring about specific desired change.

2. Even though psychoeducational interventions, in general, are designed to help almost everyone, and even if the participants are fairly homogenous, there are many important differences between individuals. Therefore, the effectiveness of psychoeducational programs are conditional. Factors such as a high sense of mastery, and age were found to attenuate the effects of certain SHIP interventions. Therefore clinicians should design interventions to meet the needs of those clients with a high sense of mastery, and take into account special needs of older and younger patients. Readiness to learn, learning style, and educational background may differ between individuals. Clinical researchers and health providers should assess the clients' readiness to learn, and be aware that readiness to learn may well be influenced by physical as well as psychological condition. Adults learn better by active participation or by interacting with others (Ventura, Young, Feldman, Pastore, Pikula & Yates, 1984).

SUMMARY

Psychoeducational interventions such as those offered by the SHIP do not act as a pill'. The prescribed 'pill', as a silver bullet alleviation for a specific condition, has been designed to be taken whole, by specific dosage, at specific intervals, over a specified duration of time. The outcome of taking the 'pill' as prescribed ('integrity') is specific and predictable.

On the other hand, psychoeducational interventions in general: 1) lack 'specificity' as to expected alleviation , 2) are not taken whole, 3) have no specific and

accurately measured dosage, 4) have no tightly controlled delivery intervals, and 5) lack tightly controlled duration. Other shortfalls of psychoeducational intervention research of methodological processes include such problems as: 1) there is a lack of 'integrity' of the treatments delivered; 2) personal characteristics differ among intervenors/teachers; and 3) outcomes are often global and variable, possibly due to measurement error.

Psychoeducational interventions, that pay attention to remediation have inherent weaknesses as discovered by treatment theory research, are a reasonable option as a treatment in helping women cope with breast cancer because there is no "cope with breast cancer" silver bullet pill. Strengthened psychoeducational interventions that address known shortfalls provide supportive care services to women with breast cancer so that they can: 1) care for themselves, 2) face adversity, 4) manage uncertainties, and 4) improve their quality of life. Eilleen, whose cancer treatment experience was described in the introduction to Chapter I, could have benefited from psychoeducational intervention such as the SHIS/UM treatment.

The offered activities potentially do the most good when there is full participation and cognitive engagement by patients. However, a wide range of individual characteristics contributes to (i.e. low mastery in the UM treatment group) or takes away from (i.e. high mastery in the UM group) women's ability to take full advantage of supportive care services and resultant benefits. If there is a way to enforce patient involvement and engagement in a 'guided' learning process that promote self-help, there

could be predictable optimum benefits to the patients, and the results would be as accurately predictable as the 'pill'. But there is no such strategy. Therefore clinical practitioners must depend on theory guided research to further refine and strengthen existing psychoeducational interventions, and to develop new alternative methods of fostering a learned self-help response to the breast cancer experience.

Appendix A

Human Subjects Approval of the SHIP Project

Human Subject Committee

THE UNIVERSITY OF
ARIZONA
HEALTH SCIENCES CENTER

1690 N. Warr[illegible] Bldg.
Tucson, Ariz[illegible] a 8572[illegible]
(602) 626-67[illegible]

26 February 1990

Carrie Jo Braden, Ph.D., R.N.
College of Nursing, 109A
Arizona Health Sciences Center

RE: HSC #A90.27 NURSE INTERVENTIONS PROMOTING SELF HELP RESPONSE TO CANCER

Dear Dr. Braden:

We received your 26 February 1990 memorandum, revised consent form, and poster for your above referenced project. The procedures to be followed in this study pose no more than minimal risk to participating subjects. Regulations issued by the U.S. Department of Health and Human Services [45 CFR Part 46.110(b)] authorize approval of this type project through the expedited review procedures, with the condition(s) that subjects' anonymity be maintained. Although full Committee review is not required, a brief summary of the project procedures is submitted to the Committee for their endorsement and/or comment, if any, after administrative approval is granted. This project is approved for one year effective 26 February 1990.

The Human Subjects Committee (Institutional Review Board) of the University of Arizona has a current assurance of compliance, number M-1233, which is on file with the Department of Health and Human Services and covers this activity.

Approval is granted with the understanding that no changes or additions will be made in study personnel, to the procedures followed or to the consent form(s) used (copies of which we have on file) without the knowledge and approval of the Human Subjects Committee and your College or Departmental Review Committee. Any research related physical or psychological harm to any subject must also be reported to each committee.

A university policy requires that all signed subject consent forms be kept in a permanent file in an area designated for that purpose by the Department Head or comparable authority. This will assure their accessibility in the event that university officials require the information and the principal investigator is unavailable for some reason.

Sincerely yours,

Milan Novak

Milan Novak, M.D., Ph.D.
Chairman
Human Subjects Committee

MN/ms

cc: Departmental/College Review Committee

File JUL 15 1991

Human Subject Committee

THE UNIVERSITY OF
ARIZONA
HEALTH SCIENCES CENTER

1690 N. Warren (Bldg. 526B) 269
Tucson, Arizona 85724
(602) 626-6721 or 626-7575

July 8, 1991

Carrie Jo Braden, Ph.D.
College of Nursing, 109A
Arizona Health Sciences Center

RE: **HSC A90.27** NURSE INTERVENTIONS PROMOTING SELF HELP RESPONSE TO CANCER

Dear Dr. Braden:

We received your 2 July 1991 letter and accompanying revised consent form for your above referenced project. Change involves extension of data collection to 6 months and 9 months, and then at 6-month intervals vs baseline, 6 weeks and 3 months. Approval for this change is granted effective 8 July 1991.

The Human Subjects Committee (Institutional Review Board) of the University of Arizona has a current assurance of compliance, number M-1233, which is on file with the Department of Health and Human Services and covers this activity.

Approval is granted with the understanding that no further changes or additions will be made either to the procedures followed or to the consent form(s) used (copies of which we have on file) without the knowledge and approval of the Human Subjects Committee and your College or Departmental Review Committee. Any research related physical or psychological harm to any subject must also be reported to each committee.

A university policy requires that all signed subject consent forms be kept in a permanent file in an area designated for that purpose by the Department Head or comparable authority. This will assure their accessibility in the event that university officials require the information and the principal investigator is unavailable for some reason.

Sincerely yours,

William F. Denny

William F. Denny, M.D.
Chairman
Human Subjects Committee

WFD:rs

cc: Departmental/College Review Committee

Human Subject Committee

THE UNIVERSITY OF
ARIZONA
HEALTH SCIENCES CENTER

1690 N. Warren (Bldg. 526B)
Tucson, Arizona 85724
(602) 626-6721 or 626-7575

August 14, 1991

Carrie Jo Braden, Ph.D.
College of Nursing, 109
Arizona Health Sciences Center

RE: **HSC A90.27** NURSE INTERVENTIONS PROMOTING SELF HELP RESPONSE TO CANCER

Dear Dr. Braden:

We received your 25 July 1991 letter in reference to your above cited project in which you request that Audrey Brooks, B.A., be allowed access to data collected from your approved intervention study for her Master's thesis. Approval of this request is granted effective 14 August 1991.

The Human Subjects Committee (Institutional Review Board) of the University of Arizona has a current assurance of compliance, number M-1233, which is on file with the Department of Health and Human Services and covers this activity.

Approval is granted with the understanding that no further changes or additions will be made either to the procedures followed or to the consent form(s) used (copies of which we have on file) without the knowledge and approval of the Human Subjects Committee and your College or Departmental Review Committee. Any research related physical or psychological harm to any subject must also be reported to each committee.

A university policy requires that all signed subject consent forms be kept in a permanent file in an area designated for that purpose by the Department Head or comparable authority. This will assure their accessibility in the event that university officials require the information and the principal investigator is unavailable for some reason.

Sincerely yours,

William F. Denny

William F. Denny, M.D.
Chairman
Human Subjects Committee

WFD:rs

cc: Departmental/College Review Committee

FEB. 1992

HUMAN SUBJECTS COMMITTEE
Periodic Review

Carrie Jo Braden / A90.27 / College of Nursing / Nurse Interventions Promoting Self Help Response to Cancer

(TITLE OF PROPOSAL)

1. What is the present state of this project:

   ☑ Continuing ☐ Closed to New Subjects ☐ Concluded

   ☐ Not Begun ☐ Not Funded

   ☐ Other _____

   *(Please specify whether or not the project should be withdrawn permanently from our active files)

2. Is the consent form as approved by the Human Subjects Committee still being used? (If not, please explain). ☑ YES ☐ NO

3. Where are the signed consent forms presently being filed? Room # 101B (If necessary check with your Department Office to ascertain filing place.)

4. Have any problems arisen in regard to the participation and safety of the people used as subjects in this project? ☐ YES ☑ NO

5. Has there been any psychological or physical injury to any subject? ☐ YES ☑ NO

6. Have any protocol changes been made that have not been approved by the Human Subjects Committee? (If yes, please submit a copy of the changes.) ☐ YES ☑ NO

This periodic review is required by Department of Health and Human Services regulations. Both the investigator's signature and that of the Chairman of the Department Review Committee is required. (The Departmental Review Committee is responsible to the Department Head for the surveillance of the ongoing project.)

Carrie Jo Braden — 1/28/92

Signature of Investigator — Date

Leann J Crosby — 1/29/92

Signature of Departmental Review Committee Chairman — Date

Please return to: University of Arizona
Human Subjects Committee
1690 N. Warren (Bldg. 526B)
Tucson, Arizona 85724

HUMAN SUBJECTS COMMITTEE COMMENTS:

HUMAN SUBJECTS COMMITTEE
PERIODIC REVIEW

FEBRUARY 1993

Carrie Jo Braden/A90.27/College of Nursing/Nurse Interventions Promoting Self Help Response to Cancer 272

Title of Proposal

1. What is the present state of this project?

☐ Continuing ☑ Closed to New Subjects ☐ Concluded

☐ Not Begun ☐ Not Funded

☐ Other*

*(Please specify whether or not the project should be withdrawn permanently from our active files)

2. Is the consent form as approved by the Human Subjects Committee still being used? (If not, please explain.) ☑ Yes ☐ No

3. Where are the signed consent forms presently being filed? Room # 109B
(If necessary check with your Department Office to ascertain filing place.)

4. Have any problems arisen in regard to the participation and safety of the people used as subjects in this project? ☐ Yes ☑ No

5. Has there been any psychological or physical injury to any subject? ☐ Yes ☑ No

6. Have any protocol changes been made that have not been approved by the Human Subjects Committee? (If yes, please submit a copy of the changes.) ☐ Yes ☑ No

This periodic review is required by the Department of Health and Human Services regulations. Both the investigator's signature and that of the Chairman of the Departmental Review Committee is required. (The Departmental Review Committee is responsible to the Department Head for the surveillance of the ongoing project.)

Carrie Jo Braden — 1/25/93
Signature of Investigator — Date

[signature] — 2/1/93
Signature of the Departmental Review Chairman — Date

Please return to: University of Arizona
Human Subjects Committee
1690 N. Warren (Bldg. 5268)
Tucson, Arizona 85724

HUMAN SUBJECTS COMMITTEE COMMENTS:

Thank you for verifying that the procedures in the above named project have not changed since last approval and that no physical or psychological harm has come to any participating subjects. This project is reapproved as of the date stamped below for a period one year. Reapproval is granted with the understanding that no changes will be made to the projects's procedures or consent form(s) without the knowledge and approval of this Committee and the College or Departmental Review Committee. Any physical or psychological harm to any subject must also be reported to each committee.

W F Denny
William F. Denny, M.D. (Chairman)

REAPPROVAL DATE: FEB 26 1993

FEBRUARY 1994 **HUMAN SUBJECTS COMMITTEE**
PERIODIC REVIEW

Carrie Jo Braden/A90.27/Nurs/Nurse Interventions Promoting Self Help Response to Cancer
NAME OF INVESTIGATOR/PROJECT APPROVAL NUMBER/TITLE OF PROPOSAL

1. What is the present status of this project?

☑ Continuing ☐ Not Begun
☑ Closed to New Subjects since 1992 ☐ Not Funded
☐ Concluded ☐ Other*

*(Please specify whether or not the project should be withdrawn permanently from our active files)

2. How many subjects enrolled at present? 242 with data across 3 pts w-drawn
   a) Number of new subjects enrolled in past 12 months (or since last approval)? NA
   b) Male/female ratio (approximate %) all women c) Number withdrawn/removed NA
3. Is the consent form as approved by the Human Subjects Committee still being used? (If not, please explain.) ☑ Yes ☐ No

   Room number where filed: 109B
   Was consent obtained for all subjects? ☑ Yes ☐ No
   Were there any problems in obtaining informed consent? ☐ Yes ☑ No
   Number of subjects refusing enrollment 85
   (Comment on refusal) too busy, no interest
   Was consent signed by subject and/or legal surrogate? ☑ Yes ☐ No
   Did all subjects receive copy of signed consent form? ☑ Yes ☐ No
4. Have any problems arisen in regard to the participation and safety of subjects in this project? ☐ Yes ☑ No
   Unanticipated adverse event(s)? ☐ Yes ☑ No

   Anticipated adverse event(s) [serious or fatal]? ☐ Yes ☑ No

   Were adverse event(s) reported to FDA? ☐ Yes ☑ No

5. Are IND or IDE drugs/devices involved? ☐ Yes ☑ No
   List IND and/or IDE number _____
6. Are subjects exposed to any source of radiation? ☐ Yes ☑ No
7. Are fetal or related tissues used? ☐ Yes ☑ No
8. Are infectious or biohazardous materials used? ☐ Yes ☑ No
9. Has there been any psychological or physical injury to any subject? ☐ Yes ☑ No
10. Have all protocol changes been submitted and approved by the Human Subjects Committee? ☑ Yes ☐ No
11. Have all new co-investigators/study collaborators been submitted for approval? ☑ Yes ☐ No
12. Has any new information become known since the date of original IRB approval that may affect the risk/benefit ratio or that would influence the willingness of the subject to continue in the study? ☐ Yes ☑ No

COMPLETE BOTH SIDES

PERIODIC REVIEW (continued)

Conflict of Interest Statement:

Do any of the investigators serve as consultant to the sponsor, the manufacturer, or to the owner of the test article?	☐ Yes ☑ No
Do any of the investigators (or their immediate family) have an equity and/or royalty relationship with the sponsor, the manufacturer, or the owner of the test article?	☐ Yes ☑ No
Has a disclosure statement been filed with the institution?	☐ Yes ☑ No NA

SUMMARIZE STUDY ACTIVITIES TO DATE [attach available research analysis or reprint(s)]

The year 5 of this project is in progress with the work being focused on analysis of existing data that was collected during the first 3 years. As noted, no new subjects have been enrolled in study this past year. We are currently resubmitting a continuation proposal - we did receive Human Subjects Approval for the proposed continuation prior to its first submission June 30, 1993 and we will neck its applicability prior to the second submission on March 1, 1994. The are no planned changes in study aims or procedures for subject recruitment and/or data collection from the June proposal in 1993.

This periodic review is required by the Department of Health and Human Services (DHHS) and the Federal Food and Drug Administration (FDA) regulations.

Carrie Jo Braden — 2/8/94

Signature of Investigator — Date

Lianne J Cross — 2/8/94

Signature of the Departmental Review Chairman — Date

Please return to: University of Arizona
Human Subjects Committee
Arizona Health Sciences Center
Tucson, Arizona 85724

IRB COMMENTS:

FEBRUARY 1995

HUMAN SUBJECTS COMMITTEE
PERIODIC REVIEW

275

Carrie Jo Braden/A90.27/Nurs/Nurse Interventions Promoting Self Help Response to Cancer
NAME OF INVESTIGATOR/PROJECT APPROVAL NUMBER/TITLE OF PROPOSAL

1. What is the present status of this project? on no cost extension until ...

☐ Continuing Enrollment ☐ Not Begun-Withdraw from active files
☑ Closed to New Subjects ☐ Not Funded-Withdraw from active files
☐ Concluded-All activity completed ☐ Other*

*(Please specify whether or not the project should be withdrawn permanently from our active files)

2. How many subjects active under the protocol or being followed at present? 0
a) Number of new subjects enrolled in past 12 months (or since last approval)? 0
b) Male/female ratio (approximate %) NA c) Number withdrawn/removed ^

3. Is the consent form as approved by the Human Subjects Committee still being used? (If not, please explain.) ☑ Yes ☐ No

Room number where filed (dept. storage site): 320 *SEE IRB COMMENTS ON REVERSE
Was consent obtained for all subjects? ☑ Yes ☐ No
Were there any problems in obtaining informed consent? ☐ Yes ☑ No
If yes, please explain:
Number of subjects refusing enrollment NA
(Comment on refusal)
Was consent signed by subject and/or legal surrogate? ☑ Yes ☐ No
Did all subjects receive copy of signed consent form? ☑ Yes ☐ No
If no, why not?

4. Have any problems arisen in regard to the participation and safety of subjects in this project? ☐ Yes ☑ No
Unanticipated adverse event(s)? ☐ Yes ☐ No

Anticipated adverse event(s) [serious or fatal]? ☐ Yes ☐ No

Were adverse event(s) reported to FDA? ☐ Yes ☐ No
N/A

5. Are IND or IDE drugs/devices involved? ☐ Yes ☑ No
List IND and/or IDE number

6. Are subjects exposed to any source of radiation? ☐ Yes ☑ No
7. Are fetal or related tissues used? ☐ Yes ☑ No
8. Are infectious or biohazardous materials used? ☐ Yes ☑ No
9. Has there been any psychological or physical injury to any subject? ☐ Yes ☑ No
10. Have all protocol changes been submitted and approved by the Human Subjects Committee? ☑ Yes ☐ No
11. Have all new co-investigators/study collaborators been submitted for approval? ☑ Yes ☐ No
12. Has any new information become known since the date of original IRB approval that may affect the risk/benefit ratio or that would influence the willingness of the subject to continue in the study? ☐ Yes ☑ No

COMPLETE BOTH SIDES

FEBRUARY 1996

HUMAN SUBJECTS COMMITTEE
PERIODIC REVIEW FORM

276

Carrie Jo Braden/A90.27/Nurs/Nurse Interventions Promoting Self Help Response to Cancer
NAME OF INVESTIGATOR/PROJECT APPROVAL NUMBER/TITLE OF PROPOSAL

1. What is the present status of this project? On no cost extension until July 1996

☐ Continuing Enrollment
☑ Closed to New Subjects
☐ Concluded-All activity completed
☐ Not Begun-Withdraw from active files
☐ Not Funded-Withdraw from active files
☐ Other*

*(Please specify whether or not the project should be withdrawn permanently from our active files)

2. How many subjects active under the protocol or being followed at present? 0
a) Number of new subjects enrolled in past 12 months (or since last approval)? 0
b) Male/female ratio (approximate %) NA
c) Number completed 305 d) Number withdrawn/removed _____

3. Is the consent form as approved by the Human Subjects Committee still being used? (If not, please explain.) ☐ Yes ☐ No
NA
Room number where filed (dept. storage site): 320
Was consent obtained for all subjects? ☑ Yes ☐ No
Were there any problems in obtaining informed consent? ☐ Yes ☑ No
If yes, please explain: _____
Number of subjects refusing enrollment NA
(Comment on refusal) _____
Was consent signed by subject and/or legal surrogate? ☑ Yes ☐ No
Did all subjects receive copy of signed consent form? ☑ Yes ☐ No
If no, why not? _____

4. Have any problems arisen in regard to the participation and safety of subjects in this project? ☐ Yes ☑ No
Unanticipated adverse event(s)? ☐ Yes ☑ No
Anticipated adverse event(s) [serious or fatal]? ☐ Yes ☑ No
Were adverse event(s) reported to FDA? ☐ Yes ☐ No
NA

5. Are IND or IDE drugs/devices involved? ☐ Yes ☑ No
List IND and/or IDE number _____

6. Are subjects exposed to any source of radiation? ☐ Yes ☑ No

7. Are fetal or related tissues used? ☐ Yes ☑ No

8. Are infectious or biohazardous materials used? ☐ Yes ☑ No

9. Has there been any psychological or physical injury to any subject? ☐ Yes ☑ No

10. Have all protocol changes been submitted and approved by the Human Subjects Committee? ☑ Yes ☐ No

11. Have all new co-investigators/study collaborators been submitted for approval? ☑ Yes ☐ No

12. Has any new information become known since the date of original IRB approval that may affect the risk-benefit ratio or that would influence the willingness of the subject to continue in the study? ☐ Yes ☑ No

COMPLETE BOTH SIDES

PERIODIC REVIEW FORM (continued)

Conflict of Interest Statement:

Do any of the investigators serve as consultant to the sponsor, the manufacturer, or to the owner of the test article?	☐ Yes ☑ No
Do any of the investigators (or their immediate family) have an equity and/or royalty relationship with the sponsor, the manufacturer, or the owner of the test article?	☐ Yes ☑ No
Has a disclosure statement been filed with the institution?	☐ Yes ☑ No

SUMMARIZE STUDY ACTIVITIES TO DATE [attach available research analysis or reprint(s); include information pertaining to enrollment of women and minorities; special issues and/or problems]

3 articles under review
10 articles in process

This periodic review is required by the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) regulations.

Carrie Jo Braden — **Signature of Investigator** — 1/11/96 — **Date**

Carolyn J. Maughan — **Signature of the Departmental Review Chairman** — 1/29/96 — **Date**

Please return to: University of Arizona
Human Subjects Committee
Arizona Health Sciences Center
Tucson, Arizona 85724

IRB COMMENTS:

The designated departmental storage site for signed consent forms is College of Nursing, Room 320.

Human Subjects Committee

THE UNIVERSITY OF
ARIZONA
HEALTH SCIENCES CENTER

1622 E. Mabel St
Tucson, Arizona 85724
(520) 626-6721

12 January 1996

Carrie J. Braden, Ph.D.
College of Nursing
Arizona Health Sciences Center

RE: **HSC A90.27** NURSE INTERVENTIONS PROMOTING SELF HELP RESPONSE TO CANCER

Dear Dr. Braden:

We received your 8 January 1996 letter and accompanying revised consent form for the above referenced project. The revised consent form has been reformatted to follow institutional guidelines; also protocol modified to include a booster self-help class six months subsequent to the self-help intervention course and the total population to be studied has been decreased to 300 from 600 [consent form revised accordingly]. Approval for these changes is granted effective 12 January 1996.

The Human Subjects Committee (Institutional Review Board) of the University of Arizona has a current assurance of compliance, number M-1233, which is on file with the Department of Health and Human Services and covers this activity.

Approval is granted with the understanding that no further changes or additions will be made either to the procedures followed or to the consent form(s) used (copies of which we have on file) without the knowledge and approval of the Human Subjects Committee and your College or Departmental Review Committee. Any research related physical or psychological harm to any subject must also be reported to each committee.

A university policy requires that all signed subject consent forms be kept in a permanent file in an area designated for that purpose by the Department Head or comparable authority. This will assure their accessibility in the event that university officials require the information and the principal investigator is unavailable for some reason.

Sincerely yours,

William F Denny

William F Denny, M.D.
Chairman
Human Subjects Committee

WFD:rs

cc: Departmental/College Review Committee

Appendix B

Human Subjects Approval of the Evaluation of the Self-Help Interventions Program: Psychoeducational Interventions for Women with Breast Cancer

College of Nursing

THE UNIVERSITY OF
ARIZONA®
HEALTH SCIENCES CENTER

1305 N. Martin
PO Box 210203
Tucson, AZ 85721-0203
(520) 626-6154

November 6, 1996

Ms. Diep Duong
University of Arizona
College of Nursing
Tucson, AZ 85721-0203

Dear Ms. Duong:

Your request to complete a secondary analysis of the data collected by Carrie Braden has been approved by the Office of Nursing Research.

We wish you success with your research.

Sincerely,

Jean Davis

Jean Davis, PhD, RN
Director of Biobehavioral Research

JD/sl

cc: Carrie Jo Braden

Appendix C

Instruments Used in this Study

I. Demographic Data

II.Arizona Social Support Interview Schedule (ASSIS)

III.Mastery Scale (MS)

IV. Self Control Schedule (SCS)

V. Inventory of Adult Role Behaviors (IARB)

VI. Mishel's Uncertainty in Illness Scale (MUIS)

VII. Positive And Negative Affect Scale (PANAS)

VIII. Idex of Well-Being (IWB)

IX. Cantril Ladder (CL)

X. Access to Self-Help Class

Self Help Intervention Project:
Breast Cancer Treatment

Demographic Data

Code # _____
Date: _____

Age: _____

Marital Status
(check one)

(6) Married _____
(5) Cohabiting (living with partner more than 6 months _____
(4) Separated _____
(3) Divorced _____
(2) Widowed _____
(1) Single/never married _____

Working/School
(check one)

(1) On medical leave from F/T job/school _____
(2) On medical leave from F/T job/school _____
(3) Retired _____
(4) Homemaker _____
(5) Part time job/school _____
(6) Full time job/school _____
(7) Other _____

Education (check one)

(1) 8th grade or less _____
(2) some high school _____
(3) high school graduate _____
(4) trade/business school _____
(5) some college _____
(6) college graduate _____
(7) graduate or professional degree _____

Family Take Home Pay (every 2 weeks)
(check one)

(1) Less than $250 _____
(2) $ 250 - 499 _____
(3) $ 500 - 749 _____
(4) $ 750 - 999 _____
(5) $1000 - 1249 _____
(6) $1250 - 1499 _____
(7) $1500 - 1749 _____
(8) $1750 - 1999 _____
(9) $2000 - 2249 _____
(10) $2250 - 2499 _____
(11) $2500 - 2749 _____
(12) $2750 - 2999 _____
(13) $3000 & above _____

Date of first Diagnosis of Breast Cancer: _____

Type of Surgery(s): (check all that apply)

	Right Breast	Left Breast	Date surgery performed Right Breast	Date surgery performed Left Breast
(1) Biopsy	_____	_____	_____	_____
(2) Radical mastectomy or Modified radical	_____	_____	_____	_____
(3) Partial mastectomy	_____	_____	_____	_____
(4) Local excision (lumpectomy)	_____	_____	_____	_____
(5) Axillary Node Dissection	_____	_____	_____	_____
(6) Breast Reconstruction	_____	_____	_____	_____

Type of Treatment(s): (check all that apply)		**Date Treatment Began** Month-Day-Year	**Date Treatment Completed** Month-Day-Year
(1) Chemotherapy	_____	_____	_____
(2) Radiation	_____	_____	_____
(3) Hormone therapy	_____	_____	_____
(4) Hyperthermia	_____	_____	_____
(5) Regular follow-up only	_____	_____	_____

Who lives at home with you? (check all that apply)

Live Alone _____
Husband _____
Children _____ (ages)
Other family _____
Friends _____
Other _____

Family History of breast cancer (check all that apply)

Mother	Sister(s)	Paternal Grandmother	Maternal Grandmother	Aunt(s)	Niece(s)	Cousins
(1)	(2)	(3)	(4)	(5)	(6)	(7)
____	____	____	____	____	____	____

Ethnic origin:

(1) White _____ (2) Hispanic _____ (3) Black _____ (4) Native American _____
(5) Oriental _____ (6) Other _____ (please indicate) _____

List of other chronic illnesses/diseases: _____

_____

Insurance coverage (check all that apply)

(1) Blue Cross/Blue Shield
(2) Commercial Insurance - e.g. Aetna
(3) HMO e.g. Intergroup, Cigna
(4) Medicare
(5) ARCCCS
(6) Self pay
(7) Other (Specify _____)

How did you discover that you had breast cancer? (check one)

_____ 1. I discovered a lump or some change in breast (swelling, discoloration, pain) during self exam.

_____ 2. A routine mammogram revealed a problem or tumor.

_____ 3. My doctor discovered lump or problem during a regular checkup.

What happened after the lump or change was discovered? (check all that apply)

_____ a) I sought prompt follow-up for diagnosis and treatment.

_____ b) I delayed prompt follow-up for diagnosis and treatment.

_____ c) Doctor directed prompt follow-up for diagnosis and treatment.

_____ d) Doctor ignored, delayed or misdiagnosed the problem, causing delayed treatment.

_____ e) Treatment was delayed due to other circumstances.

DATE: _____ ID # _____

T: _____

ASSIS

Note: Interviewer instructions are enclosed within parentheses. Response should be recorded on ASSIS answer sheet(s).

(READ TO SUBJECT):

In the next few minutes I would like to get an idea of the people who are important to you in a number of different ways. I will be reading descriptions of ways that people are often important to us. After I read each description I will be asking you to give me the first names, initials, or nicknames of the people who fit the description. These people might be friends, family members, teachers, priests, ministers, doctors, or other people who you might know.

If you have any questions about the descriptions after I read each one, please ask me to try to make it more clear.

A. (INTIMATE INTERACTION)

A1. If you wanted to talk to someone about things that are very personal and private, who would you talk to? Give me the first names, initials, or nicknames of people who you would talk to about things that are very personal and private.

(IF THE SUBJECT IS UNABLE TO NAME A SINGLE PERSON, GO TO A4.)

(IF THE SUBJECT NAMES ONE OR MORE PEOPLE, PROBE FOR ANY ADDITIONAL NAMES BY ASKING): Is there anyone else who you can think of?

A2. During the last month, which of these people did you actually talk to about things that were personal and private?

(CHECK ABOUT PEOPLE WHO WERE LISTED IS RESPONSE TO A1 BUT WHO WERE NOT LISTED IN RESPONSE TO A2)

How would you rate your satisfaction or dissatisfaction with the times you talked to people about your personal and private feelings during the past month?

Look at this card (SHOW SATISFACTION CARD) and tell me which number best describes your rating. (RECORD A NUMBER 1-7 ON ANSWER SHEET).

(IF MARRIED OR WITH PARTNER, AND IF THE SUBJECT NAMED PARTNER IN A1 AND A2, ALSO ASK) How would you rate your satisfaction or dissatisfaction with the times you talked to your husband/partner about your personal and private feelings during the past month?

Look at this card (SHOW SATISFACTION CARD) and tell me which number best describes your rating. (RECORD A NUMBER 1-7 ON ANSWER SHEET).

During the past month, how much do you think you needed people to talk to about things that were very personal and private?

Look at this card (SHOW NEED CARD) and tell me which number best describes your need. (RECORD A NUMBER 1-5 ON ANSWER SHEET).

4. (IF MARRIED OR WITH PARTNER, ALSO ASK) During the past month, how much do you think you needed your husband/partner to talk to about things that were very personal and private?

Look at this card (SHOW NEED CARD) and tell me which number best describes your need. (RECORD A NUMBER 1-5 ON ANSWER SHEET).

3. (MATERIAL AID)

B1. If you needed to borrow $25 or something valuable, who are the people you know who would lend or give you $25 or more, or would lend or give you something (a physical object) that was valuable?

You can name some of the same people that you named before if they fit this description, too, or you can name some other people.

(IF THE SUBJECT IS UNABLE TO NAME A SINGLE PERSON, GO TO B4.)

(IF THE SUBJECT NAMES ONE OR MORE PEOPLE, PROBE FOR ANY ADDITIONAL NAMES BY ASKING): Is there anyone else who you can think of?

B2. During the past month, which of these people actually loaned or gave you some money over $25 or gave or loaned you some valuable object that you needed?

(CHECK ABOUT PEOPLE WHO WERE LISTED IN RESPONSE TO B1 BUT WHO WERE NOT LISTED IN RESPONSE TO B2)

3. During the past month, how satisfied or dissatisfied were you with the things that people loaned or gave?

HOW SATISFACTION CARD, RECORD RESPONSE ON ANSWER SHEET)

3. (IF MARRIED OR WITH PARTNER, AND IF THE SUBJECT NAMED PARTNER IN B1 AND B2, ALSO ASK) During the past month, how satisfied or dissatisfied were you with the things your husband/partner loaned or gave?

HOW SATISFACTION CARD, RECORD RESPONSE ON ANSWER SHEET)

4. During the past month, how much do you think you needed people who could lend or give you things that you needed?

HOW NEED CARD, RECORD RESPONSE ON ANSWER SHEET)

4. (IF MARRIED OR WITH PARTNER, ALSO ASK) During the past month, how much do you think you needed your husband/partner to lend or give you things that you needed?

HOW NEED CARD, RECORD RESPONSE ON ANSWER SHEET)

. (ADVICE)

1. Who would you go to if a situation came up when you needed some advice?

   Remember, you can name some of the same people that you mentioned before, or you can name some new people.

F THE SUBJECT IN UNABLE TO NAME A SINGLE PERSON, GO TO C4.)

F THE SUBJECT NAMES ONE OR MORE PEOPLE, PROBE FOR ANY DDITIONAL NAMES BY ASKING): Is there anyone else who you can think of?

2. During the past month, which of these people actually gave you some important advice?

HECK ABOUT PEOPLE WHO WERE LISTED IN RESPONSE TO C1 BUT WHO ERE NOT LISTED IN RESPONSE TO C2)

3. During the past month, how satisfied or dissatisfied were you with the advice that you were given?

HOW SATISFACTION CARD, RECORD RESPONSE ON ANSWER SHEET)

$C3_1$. (IF MARRIED OR WITH PARTNER, AND IF THE SUBJECT NAMED PARTNER IN C1 AND C2, ALSO ASK) During the past month, how satisfied or dissatisfied were you with the advice your husband/partner gave you?

(SHOW SATISFACTION CARD, RECORD RESPONSE ON ANSWER SHEET)

$C4_1$. During the past month, how much do you think you needed to get advice?

(SHOW NEED CARD, RECORD RESPONSE ON ANSWER SHEET)

$C4_2$. (IF MARRIED OR WITH PARTNER, ALSO ASK) During the past month, how much do you think you needed to get advice from your husband/partner?

(SHOW NEED CARD, RECORD RESPONSE ON ANSWER SHEET)

D. (POSITIVE FEEDBACK)

D1. Who are the people who like or accept your advice? They might be people you mentioned before or new people.

(IF THE SUBJECT IS UNABLE TO NAME A SINGLE PERSON, GO TO D4.)

(IF THE SUBJECT NAMES ONE OR MORE PEOPLE, PROBE FOR ANY ADDITIONAL NAMES BY ASKING): Is there anyone else you can think about?

D2. During the past month, which of these people accepted your ideas or opinions?

(CHECK ABOUT PEOPLE WHO WERE LISTED IN RESPONSE TO D1 BUT WHO WERE NOT LISTED IN RESPONSE TO D2)

$D3_1$. During the past month, how satisfied or dissatisfied were you with the times that people told you that they like your ideas or the things that you did?

(SHOW SATISFACTION CARD, RECORD RESPONSE ON ANSWER SHEET)

$D3_2$. (IF MARRIED OR WITH PARTNER, AND IF THE SUBJECT NAMED PARTNER IN D1 AND D2, ALSO ASK) During the past month, how satisfied or dissatisfied were you with the times that your husband/partner told you that he liked your ideas or the things that you did?

(SHOW SATISFACTION CARD, RECORD RESPONSE ON ANSWER SHEET)

$D4_1$. During the past month, how much do you think you needed to have people let you know when they liked your ideas or things that you did?

(SHOW NEED CARD, RECORD RESPONSE ON ANSWER SHEET)

D4$_2$. (IF MARRIED OR WITH PARTNER, ALSO ASK) During the past month, how much do you think you needed to have your husband/partner let you know when he liked your ideas or things that you did?

(SHOW NEED CARD, RECORD RESPONSE ON ANSWER SHEET)

E. (PHYSICAL ASSISTANCE)

E1. Who are the people who you could call on to help you take care of something that you need to do -- things like driving you someplace you need to go, helping yo do some work around the house, going to the store for you, and things like that? Remember, you might have listed these people before or they could be new names.

(IF THE SUBJECT IS UNABLE TO NAME A SINGLE PERSON, GO TO E4.)

(IF THE SUBJECT NAMES ONE OR MORE PEOPLE, PROBE FOR ANY ADDITIONAL NAMES BY ASKING): Is there anyone else who you can think about?

E2. During the past month, which of these people actually pitched in to help you do things that you needed some help with?

(CHECK ABOUT PEOPLE WHO WERE LISTED IN RESPONSE TO E1 BUT WHO WERE NOT LISTED IN RESPONSE TO E2)

E3$_1$. During the past month, how satisfied or dissatisfied were you with the help you received in doing these things that you needed to do?

(SHOW SATISFACTION CARD, RECORD RESPONSE ON ANSWER SHEET)

E3$_2$. (IF MARRIED OR WITH PARTNER, AND IF THE SUBJECT NAMED PARTNER IN E1 AND E2, ALSO ASK) During the past month, how satisfied or dissatisfied were you with the help you received from your husband/partner in doing these things that you needed to do?

(SHOW SATISFACTION CARD, RECORD RESPONSE ON ANSWER SHEET)

E4$_1$. During the past month, how much do you feel you needed people who would pitch in to help you do things?

(SHOW NEED CARD, RECORD RESPONSE ON ANSWER SHEET)

E4$_2$. (IF MARRIED OR WITH PARTNER, ALSO ASK) During the past month, how much do you feel you needed your husband/partner to help you do things?

(SHOW NEED CARD, RECORD RESPONSE ON ANSWER SHEET)

F. (SOCIAL PARTICIPATION)

F1. Who are the people who you get together with to have fun or to relax? These could be new names or ones you listed before.

(IF THE SUBJECT IS UNABLE TO NAME A SINGLE PERSON, GO TO F4.)

(IF THE SUBJECT NAMES ONE OR MORE PEOPLE, PROBE FOR ANY ADDITIONAL NAMES BY ASKING): Is there anyone else who you can think about?

F2. During the past month, which of these people did you actually get together with to have fun or to relax?

(CHECK ABOUT PEOPLE WHO WERE LISTED IN RESPONSE TO F1 BUT WHO WERE NOT LISTED IN RESPONSE TO F2)

$F3_1$. During the past month, how satisfied or dissatisfied were you with the times that you got together with people just to have fun and relax?

(SHOW SATISFACTION CARD, RECORD RESPONSE ON ANSWER SHEET)

$F3_2$. (IF MARRIED OR WITH PARTNER, AND IF THE SUBJECT NAMED PARTNER IN F1 AND F2, ALSO ASK) During the past month, how satisfied or dissatisfied were you with the times you got together with your husband/partner just to have fun and relax?

(SHOW SATISFACTION CARD, RECORD RESPONSE ON ANSWER SHEET)

$F4_1$. How much do you think that you needed to get together with other people for fun and relaxation during the past month?

(SHOW NEED CARD, RECORD RESPONSE ON ANSWER SHEET)

$F4_2$. (IF MARRIED OR WITH PARTNER, ALSO ASK) How much do you think that you needed to get together with your husband/partner for fun and relaxation during the past month?

(SHOW NEED CARD, RECORD RESPONSE ON ANSWER SHEET)

G. (NEGATIVE INTERACTIONS)

G1. Who are the people who you argue with or who make you angry and upset? These could be new names or names you listed before.

(IF NO ONE IS IDENTIFIED, GO TO H)

G2. During the past month, which of these people have you had arguments with or have made you angry and upset?

(CHECK ABOUT PEOPLE WHO WERE LISTED IN RESPONSE TO G1 BUT WHO WERE NOT LISTED IN RESPONSE TO G2)

H. (PERSONAL CHARACTERISTICS OF NETWORK MEMBERS)

Now I would like to get some information about the people you have just listed. (FOR EACH PERSON ON THE LIST) Could you tell me:

Ha. What is this person's relationship to you?

Hb. How old is this person?

Hc. What is this person's sex?

Hd. What is this person's ethnicity? (SHOW RACE/ETHNICITY CARD)

1 = Black
2 = non-Hispanic Caucasian
3 = Mexican, Chicano, Latino, Hispanic
4 = American Indian
5 = Asian
6 = other

DATE: _____ ID # _____

T: _____

MS

Read the following statements and make a mark on the straight line that best describes the judgment that you make about the questions TODAY.

1. There is really no way I can solve some of the problems I have.

   Strongly agree _____ Strongly disagree

2. Sometimes I feel that I'm being pushed around in life.

   Strongly agree _____ Strongly disagree

3. I have little control over things that happen to me.

   Strongly agree _____ Strongly disagree

4. I can do just about anything I really set my mind to do.

   Strongly disagree _____ Strongly agree

5. I often feel helpless in dealing with the problems in life.

   Strongly agree _____ Strongly disagree

6. What happens to me in the future depends on me.

   Strongly disagree _____ Strongly agree

7. There is little I can do to change many important things in my life.

   Strongly agree _____ Strongly disagree

DATE _____ ID # _____ 292

T _____

SCS

Read the following statements and place a mark at the point on the corresponding line that best fits you TODAY.

1. When I do a boring job, I think about the less boring parts of the job and the reward I will receive once I am finished.

Not true about me _____ True about me

2. When I have to do something that is anxiety arousing for me, I try to visualize how I will overcome my anxieties while doing it.

Not true about me _____ True about me

3. Often by changing my way of thinking I am able to change my feelings about almost anything.

Not true about me _____ True about me

4. I often find it difficult to overcome my feelings of nervousness and tension without any outside help.

True about me _____ Not true about me

5. When I am feeling depressed I try to think about pleasant events.

Not true about me _____ True about me

6. I cannot avoid thinking about mistakes I have made in the past.

True about me _____ Not true about me

7. When I am faced with a difficult problem, I try to approach its solution in a systematic way.

Not true about me _____ True about me

8. I usually do my duties quicker when somebody is pressuring me.

True about me _____ Not true about me

9. When I find that I have difficulties in concentrating on my reading, I look for ways to increase my concentration.

Not true about me _____ True about me

10. When I try to get rid of a bad habit, I first try to find out all the factors that maintain this habit.

Not true about me _____ True about me

11. When an unpleasant thought is bothering me, I try to think about something pleasant.

Not true about me _____ True about me

12. If I smoked two packages of cigarettes a day, I probably would need outside help to stop smoking.

True about me _____ Not true about me

13. When I am in a low mood, I try to act cheerful so my mood will change.

Not true about me _____ True about me

14. If I had the pills with me, I would take a tranquilizer whenever I felt tense and nervous.

True about me _____ Not true about me

15. When I am depressed, I try to keep myself busy with things that I like.

Not true about me _____ True about me

16. I tend to postpone unpleasant duties even if I could perform them immediately.

Not true about me _____ True about me

17. When I find it difficult to settle down and do a certain job, I look for ways to help me settle down.

Not true about me _____ True about me

18. Although it makes me feel bad, I cannot avoid thinking about all kinds of possible catastrophes in the future.

True about me _____ Not true about me

19. First of all I prefer to finish a job that I have to do and then start doing the things I really like.

True about me _____ Not true about me

20. When I feel discomfort in a certain part of my body, I try not to think about it.

True about me _____ Not true about me

21. My self-esteem increases once I am able to overcome a bad habit.

Not true about me _____ True about me

22. In order to overcome bad feelings that accompany failure, I often tell myself that it is not so catastrophic and that I can do something about it.

Not true about me _____ True about me

23. When I feel that I am too impulsive, I tell myself stop and think before you do anything.

Not true about me _____ True about me

24. Even when I am terribly angry at somebody, I consider my actions very carefully.

Not true about me _____ True about me

25. Facing the need to make a decision, I usually find out all the possible alternatives instead of deciding spontaneously without thought.

Not true about me _____ True about me

26. Usually I first do the things I really like to do even if there are more urgent things to do.

Not true about me _____ True about me

27. When I realize that I cannot help but be late for an important meeting, I tell myself to keep calm.

Not true about me _____ True about me

28. I usually plan my work when faced with a number of things to do.

Not true about me _____ True about me

29. When I am short of money, I decide to record all my expenses in order to plan more carefully in the future.

Not true about me _____ True about me

30. If I find it difficult to concentrate on a certain job, I divide the job into smaller segments.

Not true about me _____ True about me

31. Quite often I cannot overcome unpleasant thoughts that bother me.

True about me _____ Not true about me

32. Once I am hungry and unable to eat, I try to divert my thoughts away from my stomach or try to imagine that I am satisfied.

Not true about me _____ True about me

Date _____ ID # _____ 296

T _____

IARB

Read the following statements and place a mark at the point on the line that best fits you TODAY.

1. Because of my illness and/or treatment I go out to social events

Less than I used to _____ The same or more than I used to

2. Because of my illness and/or treatment I am doing shopping and errands

Less than I used to _____ The same or more than I used to

3. I am able to participate in the social activities that I want to do

Less than I used to _____ The same or more than I used to

4. I am doing the community activities that I want to do

Less than I used to _____ The same or more than I used to

5. I am doing recreational activities that I like to do

Less than I used to _____ The same or more that I used to

6. I stay home

More than I used to _____ The same or less than I used to

7. My illness has disrupted my friendships to the

Highest degree possible _____ Least degree possible

8. Because of my illness or treatment I stay away from the rest of my family to the

Highest degree possible _____ Least degree possible

9. I act irritable toward family members (for example, snap at them, criticize them, pick fights) to the

Greatest extent possible _____ Least extent possible

10. My illness or treatment interferes with the regular daily work around the house I usually do (for example, yard work repairs, cooking, cleaning, etc) to the

Highest degree possible _____ Least degree possible

11. My illness interferes with the length of visits with my friends to the

Greatest extent possible _____ Least extent possible

12. My illness or treatment interferes with the things I usually do for fun to the

Greatest extent possible _____ Least extent possible

13. I have influence in my family appropriate to my place in the family (i.e., as wife, daughter, grandmother, sister, etc.) to the

Least extent possible _____ Greatest extent possible

14. I am involved in a variety of rewarding social activities to the

Least extent possible _____ Greatest extent possible

15. My leisure time is occupied with a variety of rewarding activities to the

Least extent possible _____ Greatest extent possible

16. My physical limitations on sexual activity affect me to the

Greatest extent possible _____ Least extent possible

DATE: _____ ID #: _____

T: _____

MUIS

Instructions: Please read each statement. Take your time and think about what each statement says. Then make a mark on the straight line that most closely measures how you were feeling the **PAST WEEK**. Please respond to every statement.

1. I don't know what is wrong with me.

Strongly Disagree _____ Strongly Agree

2. I have a lot of questions without answers.

Strongly Disagree _____ Strongly Agree

3. I am unsure if my illness is getting better or worse.

Strongly Disagree _____ Strongly Agree

4. I don't know how bad my discomfort will be.

Strongly Disagree _____ Strongly Agree

5. The explanations they give about my condition are hazy to me.

Strongly Disagree _____ Strongly Agree

6. The purpose of each treatment is clear to me.

Strongly Agree _____ Strongly Disagree

7. When I have discomfort, I know what this means about my condition.

Strongly Agree _____ Strongly Disagree

8. I do not know when to expect things will be done to me.

Strongly Disagree _____ Strongly Agree

9. My symptoms continue to change unpredictably.

Strongly Disagree _____ Strongly Agree

10. I understand everything explained to me.

Strongly Agree _____ Strongly Disagree

11. The doctors say things to me that could have many meanings.

Strongly Disagree _____ Strongly Agree

12. I can predict how long my illness will last.

Strongly Agree _____ Strongly Disagree

13. My treatment is too complex to figure out.

Strongly Disagree _____ Strongly Agree

14. It is difficult to know if the treatments or medications I am getting are helping.

Strongly Disagree _____ Strongly Agree

15. Because of the unpredictability of my illness, I cannot plan for the future.

Strongly Disagree _____ Strongly Agree

16. The course of my illness keeps changing; I have good and bad days.

Strongly Disagree _____ Strongly Agree

17. It's vague to me how I will manage my care.

Strongly Disagree _____ Strongly Agree

18. I have been given many differing opinions about what is wrong with me.

Strongly Disagree _____ Strongly Agree

19. It is not clear what is going to happen to me.

Strongly Disagree _____ Strongly Agree

20. I usually know if I am going to have a good or bad day.

Strongly Agree _____ Strongly Disagree

21. The results of my tests are inconsistent.

Strongly Disagree _____ Strongly Agree

22. The effectiveness of the treatment is unknown.

Strongly Disagree _____ Strongly Agree

23. It is difficult to determine how long it will be before I can care for myself.

Strongly Disagree _____ Strongly Agree

24. I can generally predict the course of my illness.

Strongly Agree _____ Strongly Disagree

25. Because of the treatment, what I can do and cannot do keeps changing.

Strongly Disagree _____ Strongly Agree

26. I'm certain they will not find anything else wrong with me.

Strongly Agree _____ Strongly Disagree

27. The treatment I am receiving has a known probability of success.

Strongly Agree _____ Strongly Disagree

28. They have not given me a specific diagnosis.

Strongly Disagree _____ Strongly Agree

29. My physical distress is predictable; I know when it is going to get better or worse.

Strongly Agree _____ Strongly Disagree

30. My diagnosis is definite and will not change.

Strongly Agree _____ Strongly Disagree

31. I can depend on the nurses to be there when I need them.

Strongly Agree _____ Strongly Disagree

32. The seriousness of my illness has been determined.

Strongly Agree _____ Strongly Disagree

33. The doctors and nurses use everyday language so I can understand what they are saying.

Strongly Agree _____ Strongly Disagree

DATE _____ ID # _____

T _____

PANAS

This scale consists of a number of words that describe different feelings and emotions that you might have regarding your illness. Read each word and then indicate to what extent you have felt this way TODAY. Use the following scale to record your answers.

1	2	3	4	5
very slightly or not at all	a little	moderately	quite a bit	extremely

_____	interested	_____	irritable
_____	distressed	_____	alert
_____	excited	_____	ashamed
_____	upset	_____	inspired
_____	strong	_____	nervous
_____	guilty	_____	determined
_____	scared	_____	attentive
_____	hostile	_____	jittery
_____	enthusiastic	_____	active
_____	proud	_____	afraid

DATE: _____ ID # _____

T: _____ 303

IWB

Here are some words and phrases which I would like you to use to describe how you feel about your present life. Put a mark on the line that best describes how you feel TODAY about your life.

1. My present life is

Boring _____ Interesting

2. My present life is

Miserable _____ Enjoyable

3. My present life is

Useless _____ Worthwhile

4. My present life is

Lonely _____ Friendly

5. My present life is

Empty _____ Full

6. My present life is

Discouraging _____ Hopeful

7. My present life is

Disappointing _____ Rewarding

8. My present life

Doesn't give me much chance _____ Brings out the best in me

9. In thinking about my life as a whole, I am

Completely dissatisfied _____ Completely satisfied

10. My present life is

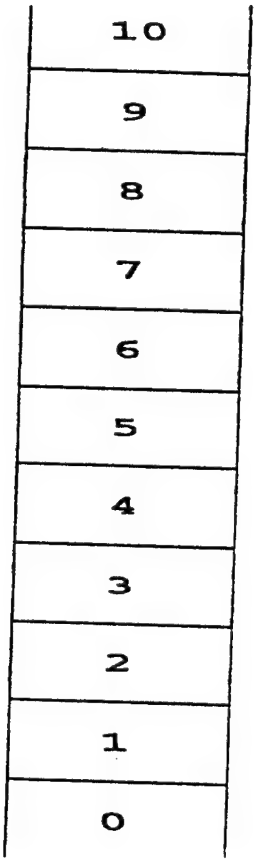
The worst it could possibly be _____ The best it could possibly be

1/90

: _____ ID # _____

_____

CL



TIONS

is a picture of a ladder. Suppose we say that the top of the ladder represents
est possible life for you and the bottom represents the worst possible life for

ere on the ladder do you feel you personally stand at the present time?
ep number _____

y did you select that number? _____

_____

ere on the ladder would you say you will stand six months from now?
ep number _____

ere do you think you will be on the ladder five years from now?
ep number _____

Access to Self-Help Class

						T1: 2 wks	T2: 4 wks	T3: 6wk
	Not Satis.	Only Slight Satis.	Satis.	Very Satis.	Extremely Satis.			
01. Think back to the state of your condition two weeks ago. How satisfied were you <u>two weeks ago</u> with the state of your condition then?	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
02. How long does it take you to travel to the site where the Self-Help Class is held?		travel time: <u>hours:minutes</u> travel distance: <u>miles</u>				__:__ _____	__:__ _____	__:__ _____
03. Do you <u>usually</u> take time off from work in order to go to the Self-Help Classes?				0 No 1 Yes.		0 No 1 Yes	0 No 1 Yes	0 No 1 Yes
		How much time is involved? <u>Hours:minutes</u>				__:__	__:__	__:__
04. Do you <u>usually</u> have to get someone to care for a family member in order to go to the Self-Help Classes?				No 1 Yes.		0 No 1 Yes	0 No 1 Yes	0 No 1 Yes
		Cost of caregiver for each class				$_____	$_____	$_____

05. Do you usually have to stay in a hotel in order to go to Self-Help Classes?		0 No 1 Yes.		0 No 1 Yes		0 No 1 Yes		0 No 1 Yes
	Cost of hotel for each class			$_____		$_____		$_____

06. When you go to the Self-Help Class, does your family at home, or other family/friends:

	Family At home (Circle one)	Other Family/ Friend (Circle one)	Husband/ F.M.	Fr.	Husband/ F.M.	Fr.	Husband/ F.M.	Fr.
a) usually drive you to/from the class?	No -- Yes	No -- Yes	N - Y	N - Y	N - Y	N - Y	N - Y	N - Y
b) usually wait for you or do errands?	No -- Yes	No -- Yes	N - Y	N - Y	N - Y	N - Y	N - Y	N - Y
c) usually have to take time off from work to accompany you?	No -- Yes	No -- Yes	N - Y	N - Y	N - Y	N - Y	N - Y	N - Y
If someone has to take time off from work, how much time is involved?	Hours:minutes		___:___		___:___		___:___	

07. During the PAST TWO WEEKS, how much did the Self-Help Class instructor usually tell you about your condition and what you can do to manage it?	1) a great deal	1	1	1
	2) a moderate amount	2	2	2
	3) a little	3	3	3
	4) almost nothing	4	4	4
	5) nothing at all	5	5	5

08. During the PAST TWO WEEKS, how satisfied were you with the following aspects of your Self-Help Class?

	Not Satis.	Only Slight Satis.	Satis.	Very Satis.	Extremely Satis.			
a. Amount of time it took to get to the class	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
b. Cost of getting to class	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
c. Overall convenience of getting to the class	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
d. Information provided by class	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
e. Amount of time spent with class instructor	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
f. Additional reading material supplied by class instructor	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
g. Improvement in your understanding of your condition	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
h. Improvement in your ability to manage your condition	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5

09. How satisfied are you <u>overall</u> with the self-help classes?

1 2 3 4 5 1 2 3 4 5 1 2 3 4 5 1 2 3 4 5

10. How satisfied are you <u>overall</u> with the state of your condition <u>now</u>?

1 2 3 4 5 1 2 3 4 5 1 2 3 4 5 1 2 3 4 5

11. Any other comments?

Access to Nurse Case Manager

	Not Satis.	Only Slight Satis.	Satis.	Very Satis.	Extremely Satis.	T1: 2 wks	T2: 4 wks	T3: 6wk
Q1. Think back to the state of your condition two weeks ago. How satisfied were you two weeks ago with the state of your condition then?	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5

Q2. During the PAST TWO WEEKS, did you feel the need to telephone the Nurse Case Manager about some special problem in managing your condition?

0 = No [Skip to Q. 3]
1 = Yes . . .

T1: 2 wks	T2: 4 wks	T3: 6wk
a. No Yes 0 1	a. No Yes 0 1	a. No Yes 0 1

(a) How much time have you spent trying to reach the Nurse Case Manager?

Hours:minutes

T1: 2 wks	T2: 4 wks	T3: 6wk
___ : ___	___ : ___	___ : ___

(b) If you decided you needed to contact the Nurse Case Manager, how long did you wait to call after you or your family first noticed the problem?

	T1: 2 wks	T2: 4 wks	T3: 6wk
# minutes [Skip to Q. 3]	_____	_____	_____
# hours [Skip to Q. 3]	_____	_____	_____
# days [Ask c]	_____	_____	_____
Did not call at all [Ask c]	_____	_____	_____

(9) If you did not call or you waited one or more days before contacting the Nurse Case Manager, please indicate which of the following reasons listed below explains why you waited (check all that apply).

a. was afraid the Nurse Case Manager would not be able to speak Spanish (01) No-Yes	No Yes 0 1	No Yes 0 1	No Yes 0 1
b. just didn't get around to calling the Nurse Case Manager (02) No-Yes	No Yes 0 1	No Yes 0 1	No Yes 0 1
c. thought it would take too long to reach the Nurse Case Manager (03) No-Yes	No Yes 0 1	No Yes 0 1	No Yes 0 1
d. felt another type of practitioner might help (04) No-Yes	No Yes 0 1	No Yes 0 1	No Yes 0 1
e. felt I could manage/treat the problem myself (05) No-Yes	No Yes 0 1	No Yes 0 1	No Yes 0 1
f. didn't think the problem was serious enough (06) No-Yes	No Yes 0 1	No Yes 0 1	No Yes 0 1
g. thought the Nurse Case Manager couldn't do anything for the problem (07) No-Yes	No Yes 0 1	No Yes 0 1	No Yes 0 1
h. feel uncomfortable with the Nurse Case Manager (08) No-Yes	No Yes 0 1	No Yes 0 1	No Yes 0 1
i. have a fear of Nurse Case Manager (09) No-Yes	No Yes 0 1	No Yes 0 1	No Yes 0 1
j. didn't want to bother the Nurse Case Manager (10) No-Yes	No Yes 0 1	No Yes 0 1	No Yes 0 1
k. was afraid to find out something was wrong (11) No-Yes	No Yes 0 1	No Yes 0 1	No Yes 0 1

l. other reasons (specify: _____) (12) No-Yes

	No	Yes		No	Yes		No	Yes
	0	1		0	1		0	1

IF YOU HAVE INDICATED MORE THAN ONE REASON, which of these reasons would you say was the main reason for not contacting the Nurse Case Manager sooner?

Reason # ____ _____ _____ _____

03. During the PAST TWO WEEKS, how satisfied were you with the following aspects of your phone contacts with the Nurse Case Manager?

	Not Satis.	Only Slight Satis.	Satis.	Very Satis.	Extremely Satis.			
a. Amount of time it took you to contact the Nurse Case Manager	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
b. Availability of Nurse Case Manager over phone	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
c. Overall convenience of contacting Nurse Case Manager	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
d. Information provided by Nurse Case Manager	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
e. Amount of time spent with Nurse Case Manager on the phone	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
f. Improvement in your understanding of your condition	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
g. Improvement in your ability to manage your condition	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5

04. How satisfied are you <u>overall</u> with the Nurse Case Manager?

1 2 3 4 5 1 2 3 4 5 1 2 3 4 5 1 2 3 4 5

05. How satisfied are you <u>overall</u> with the state of your condition <u>now</u>?

1 2 3 4 5 1 2 3 4 5 1 2 3 4 5 1 2 3 4 5

06. Any other comments?

	Not Satis.	Only Slight Satis.	Satis.	Very Satis.	Extremely Satis.	T1: 2 wks	T2: 4 wks	T3: 6wk
01. Think back to the state of your condition two weeks ago. How satisfied were you <u>two weeks ago</u> with the state of your condition then?	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
02. During the PAST TWO WEEKS, how much time did <u>your husband/family</u> spend with you in doing the Home Study program?						<u>hours:minutes</u> :	:	:
03. During the PAST TWO WEEKS, how much time did <u>you</u> spend doing the Home Study program?						<u>hours:minutes</u> :	:	:

04. During the PAST TWO WEEKS, How satisfied were you with the following aspects of the Independent Learning program?

	Not Satis.	Only Slight Satis.	Satis.	Very Satis.	Extremely Satis.	T1: 2 wks	T2: 4 wks	T3: 6wk
a. Amount of time it took you to complete the Home Study lessons	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
b. Overall convenience of Home Study lessons	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
c. Information provided by Home Study lessons	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
d. Additional reading material contained in Home Study lessons	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5

e. Improvement in your understanding of your condition	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5
f. Improvement in your ability to manage your condition	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5

05. How satisfied are you <u>overall</u> with the Independent Learning Program?

	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5

06. How satisfied are you <u>overall</u> with the state of your condition <u>now</u>?

	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5

07. Any other comments?

Control Group

	Not Satis.	Only Slight Satis.	Satis.	Very Satis.	Extremely Satis.	T1: 2 wks	T2: 4 wks	T3: 6wk
01. Think back to the state of your condition two weeks ago. How satisfied were you two weeks ago with the state of your condition then?	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
02. During the PAST TWO WEEKS, How satisfied were you with the following aspects of your treatment?								
a. Verbal information provided by physician	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
b. Verbal information provided by nurses	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
c. Additional reading material supplied by physician or nurses	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
d. Improvement in your understanding of your condition	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
e. Improvement in your ability to manage your condition	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
03. How satisfied are you overall with your treatment?	1	2	3	4	5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5

DATE: _____ ID #: _____

T: _____ Interviewer: _____

ASSIS ANSWER SHEET

Network Members	A		B		C		D		E		F		G		REL	AGE	SEX	ETH
	1	2	1	2	1	2	1	2	1	2	1	2	1	2				
1.																		
2.																		
3.																		
4.																		
5.																		
6.																		
7.																		
8.																		
9.																		
10.																		
11.																		
12.																		
13.																		
14.																		
15.																		

Relationship
1. spouse/partner
2. immediate family (son, daughter)
3. extended family (mother, father, sister, brother, aunt, etc)
4. friend
5. neighbor
6. work associate
7. spiritual advisor
8. health care
9. other

SEX
0 = male
1 = female

ETHNICITY
1. Black
2. non-Hispanic Caucasian
3. Mexican, Latino Hispanic
4. American Indian
5. Asian
6. Other

3_1 ____	3_1 ____	3_1 ____	3_1 ____	3_1 ____	3_1 ____	
3_2 ____	3_2 ____	3_2 ____	3_2 ____	3_2 ____	3_2 ____	
4_1 ____	4_1 ____	4_1 ____	4_1 ____	4_1 ____	4_1 ____	
4_2 ____	4_2 ____	4_2 ____	4_2 ____	4_2 ____	4_2 ____	

_____ Total 1 No. with (✓) in Col. 1 of at least one of A-F col.

_____ Total 2 No. with (✓) in Col. 2 of at least one in A-F col.

_____ Total 3_1 Total of row 3_1

_____ Total 3_2 Total of row 3_2

_____ Total 4_1 Total of row 4_1

_____ Total 4_2 Total of row 4_2

* Total 2 can never be more than Total 1

1/90

Appendix D
Quantification of SHIP Treatment Strength

Quantification of Treatment Strength Of The Self-Help Intervention Project (SHIP)

As an expert in the area of oncology, intervention research, and/or program evaluation, you are being asked to rank the following indicators which contribute to the strength of a psychoeducational intervention. The results assist in determining how much of the intervention actually was delivered to the patients. Thank you for your participation.

PART A

Context: Overall, SHIP is a set of psychoeducational interventions expected to 1) enhance clients' knowledge of breast cancer, its treatment, the treatment side effects, and available patient resources; 2) improve clients' coping/enabling skills for problem solving; and 3) help clients deal with uncertainty.

Directions for Part A - From your experience, rank the contribution of the following indicators for efficacy of the **entire** SHIP intervention.

Please rank each indicator on a scale 1-5 with 5 being the highest contribution. The most critical indicator gets the highest rank.

For example: If the POTENCY indicator is most critical (ranked 5), it means that it is extremely critical whether or not an intervenor was adequately educated or trained to provide the intended intervention.

TREATMENT STRENGTH INDICATORS	Ranking of Indicators
Potency Indicator Definition: Educational/training/preparation level of the intervenors	
Specificity Indicator Definition: Specified active ingredients in the intervention i.e. behavioral, cognitive, etc	
Purity Indicator Definition: Whether or not the intervention has written protocol for delivery	
Intensity Indicator Definition: Proportion of the intervention that patients actually received	
Frequency Indicator Definition: How often the intervention is scheduled to be delivered i.e. daily, weekly, monthly, etc.	

PART B

Context: The SHIP has 3 main intervention components.
SHIS = **S**elf-**H**elp **I**ndependent **S**tudy.....self-study and self-paced study of 6 lessons regarding breast cancer and related issues.
SHC = **S**elf-**H**elp **C**lass.....same content as SHIS but delivered for 6 weeks by trained teacher in small group.
UM = **U**ncertainty **M**anagement.....contacts with nurse-client manager by phone a minimum of once weekly for 6 weeks.

Directions for Part B - From your experience, indicate how much the **POTENCY <u>indicator</u>** (education/training level of the intervenors) contributes to the efficacy of **<u>SHIS and SHC components</u>** of SHIP interventions? Please indicate on a scale 1-3, with 3 being highest.

For example: If having a masters prepared teacher is important for SHC component, then SHC receives a score of 2.

Potency Indicator - Education/training level of the intervenors	Not at all important	Some what important	Very important
How important is the intervenor of SHC is PhD prepared	1	2	3
How important is the intervenor of UM is PhD prepared	1	2	3
How important is the intervenor of SHC is masters prepared	1	2	3
How important is the intervenor of UM is masters prepared	1	2	3

Appendix E
1.Samples of SAS Program for Individual Growth Curve Analysis
2.Sample of SAS Program for Creating Group Means From Individuals' Slopes and Plotting Group Mean

SAS Program For Reading SPSS 'POR' Dataset' Sort And Output To Permanent SAS Dataset, Then Creating Individual Growth Curve For Each Variable

```
libname perm '.' ;
options nocenter ;
linesize=80  nonotes ;

libname x spss 'fs.por' ;

data perm.ship1 ;
set x._first_ ;

array assis(6) assism1 assism2 assism3 assism4 assism5 assism6 ;
array ms(6) msm1 msm2 msm3 msm4 msm5 msm6 ;
array scs1(6) scs1m1 scs1m2 scs1m3 scs1m4 scs1m5 scs1m6 ;
array scs2(6) scs2m1 scs2m2 scs2m3 scs2m4 scs2m5 scs2m6 ;
array scs3(6) scs3m1 scs3m2 scs3m3 scs3m4 scs3m5 scs3m6 ;
array iarb(6) iarbm1 iarbm2 iarbm3 iarbm4 iarbm5 iarbm6 ;
array muis(6) muism1 muism2 muism3 muism4 muism5 muism6 ;
array naf(6) nafm1 nafm2 nafm3 nafm4 nafm5 nafm6  ;
array iwb(6) iwbm1 iwbm2 iwbm3 iwbm4 iwbm5 iwbm6 ;

if cell^=. ;
do time = 0 to 5 ;
  newassis=assis(time+1) ;
  newms=ms(time+1) ;
  newscs1=scs1(time+1) ;
  newscs2=scs2(time+1) ;
  newscs3=scs3(time+1) ;
  newiarb=iarb(time+1) ;
  newmu=mu(time+1) ;
  newmuis=muis(time+1) ;
  newnaf=naf(time+1) ;
  newiwb=iwb(time+1) ;
keep sid cell medicfs time newassis newms newscs1 newscs2
     newscs3 newiarb newmu newmuis
     newnaf newiwb ;
output ;
end ;

proc sort data=perm.ship1 ;
 by cell sid time ;
endsas ;
```

SAS Program For Reading In Permanent SAS Dataset As Temporary File, Then Run Individual Regressions For Each Variable

```
/*Merge dataset: parameter est, sid, cell into temp
dataset=combine**/

libname perm '.' ;
options nocenter nonotes ;
data ship ;
  set perm.ship1 ;

%macro iter(i,varname) ;
proc reg noprint data=ship outest=curve&i ;
  model &varname =time ;
  by cell sid ;
run ;

%mend iter ;
%iter(1,newassis) ;
%iter(2,newms) ;
%iter(3,newscs1) ;
%iter(3,newscs2) ;
%iter(3,newscs3) ;
%iter(4,newiarb) ;
%iter(5,newmu) ;
%iter(6,newmuis) ;
%iter(7,newnaf) ;
%iter(8,newiwb) ;

data perm.combine ;
  merge curve1(keep=cell sid intercep time
               rename=(intercep=newassi0 time=newassi1))
        curve2(keep=cell sid intercep time
               rename=(intercep=newms0 time=newms1))
        curve3(keep=cell sid intercep time
               rename=(intercep=newscs10 time=newscs11))
        curve4(keep=cell sid intercep time
               rename=(intercep=newscs20 time=newscs21))
        curve5(keep=cell sid intercep time
               rename=(intercep=newscs30 time=newscs31))
```

```
        curve6(keep=cell sid intercep time
              rename=(intercep=newiarb0 time=newiarb1))
        curve7(keep=cell sid intercep time
              rename=(intercep=newmu0 time=newmu1))
        curve8(keep=cell sid intercep time
              rename=(intercep=newmuis0 time=newmuis1))
        curve9(keep=cell sid intercep time
              rename=(intercep=newnaf0 time=newnaf1))
        curve10(keep=cell sid intercep time
              rename=(intercep=newiwb0 time=newiwb1))
by cell sid ;
proc print data=perm.combine ;

proc glm ;
  class cell ;
  model newmu0 newassi0 newscs11 newscs21 newscs31 newiarb1
        newmuis1 newnaf1 newiwb1 = cell ;
  means cell ;

proc glm ;
  class cell ;
  model newscs11 newscs21 newscs31 newiarb1 newmuis1 newnaf1
        newiwb1 = newms0 ;
  means cell ;

proc glm ;
  class cell ;
  model newscs11 newscs21 newscs31 newiarb1 newmuis1 newnaf1
        newiwb1 = newassi0 ;

proc means mean var std max min t prt maxdec=2 ;
 class cell ;
 where _depvar_^='' ;
 by _depvar_ ;
 var intercept time ;
 output ;*/
```

```
/* exporting sas dataset to SPSS portable dataset for
further analysis*/

data perm.expdata1 ;
set perm.combine ;
file 'expdata1' linesize=250;
lrecl=250 ;
put (cell sid newassi0 newassi1 newms0 newms1 newscs10
newscs11 newscs20 newscs21 newscs30 newscs31 newiarb0
newiarb1 newmu0 newmu1 newmuis0 newmuis1 newnaf0 newnaf1
newiwb0 newiwb1) (10.5);
run;
```

SAS Program For Reading In Permanent SAS Dataset As Temporary File, Then Run Individual Regressions

```
/*Merge dataset: parameter est, sid, cell into temp
dataset=combine**/

libname perm '.' ;
options nocenter nonotes ;
data ship ;
  set perm.ship1 ;

%macro iter(i,varname) ;
proc reg noprint data=ship outest=curve&i ;
  model &varname =time ;
  by cell sid ;
run ;
%mend iter ;
%iter(1,newassis) ;
%iter(2,newms) ;
%iter(3,newscs1) ;
%iter(3,newscs2) ;
%iter(3,newscs3) ;
%iter(4,newiarb) ;
%iter(5,newmu) ;
%iter(6,newmuis) ;
%iter(7,newnaf) ;
%iter(8,newiwb) ;

data perm.combine ;
  merge curve1(keep=cell sid intercep time
               rename=(intercep=newassi0 time=newassi1))
        curve2(keep=cell sid intercep time
               rename=(intercep=newms0 time=newms1))
        curve3(keep=cell sid intercep time
               rename=(intercep=newscs10 time=newscs11))
        curve4(keep=cell sid intercep time
               rename=(intercep=newscs20 time=newscs21))
        curve5(keep=cell sid intercep time
               rename=(intercep=newscs30 time=newscs31))
        curve6(keep=cell sid intercep time
               rename=(intercep=newiarb0 time=newiarb1))
```

```
        curve7(keep=cell sid intercep time
              rename=(intercep=newmu0 time=newmu1))
        curve8(keep=cell sid intercep time
              rename=(intercep=newmuis0 time=newmuis1))
        curve9(keep=cell sid intercep time
              rename=(intercep=newnaf0 time=newnaf1))
        curve10(keep=cell sid intercep time
              rename=(intercep=newiwb0 time=newiwb1))
by cell sid ;
proc print data=perm.combine ;
```

SAS Program For Reading SPSS 'POR' Dataset' Sort And Output To Permanent SAS Dataset, Then Creating Individual Growth Curve For Each Variable

```
libname perm '.' ;
options nocenter ;
linesize=80  nonotes ;

libname x spss 'fs.por' ;

data perm.ship1 ;
set x._first_ ;

array assis(6) assism1 assism2 assism3 assism4 assism5 assism6 ;
array ms(6) msm1 msm2 msm3 msm4 msm5 msm6 ;
array scs1(6) scs1m1 scs1m2 scs1m3 scs1m4 scs1m5 scs1m6 ;
array scs2(6) scs2m1 scs2m2 scs2m3 scs2m4 scs2m5 scs2m6 ;
array scs3(6) scs3m1 scs3m2 scs3m3 scs3m4 scs3m5 scs3m6 ;
array iarb(6) iarbm1 iarbm2 iarbm3 iarbm4 iarbm5 iarbm6 ;
array muis(6) muism1 muism2 muism3 muism4 muism5 muism6 ;
array naf(6) nafm1 nafm2 nafm3 nafm4 nafm5 nafm6  ;
array iwb(6) iwbm1 iwbm2 iwbm3 iwbm4 iwbm5 iwbm6 ;

if cell^=. ;
do time = 0 to 5 ;
  newassis=assis(time+1) ;
  newms=ms(time+1) ;
  newscs1=scs1(time+1) ;
  newscs2=scs2(time+1) ;
  newscs3=scs3(time+1) ;
  newiarb=iarb(time+1) ;
  newmu=mu(time+1) ;
  newmuis=muis(time+1) ;
  newnaf=naf(time+1) ;
  newiwb=iwb(time+1) ;
keep sid cell medicfs time newassis newms newscs1 newscs2
     newscs3 newiarb newmu newmuis
     newnaf newiwb ;
output ;
end ;

proc sort data=perm.ship1 ;
 by cell sid time ;
endsas ;
```

SAS Program For Reading In Permanent SAS Dataset As Temporary File, Then Run Individual Regressions For Each Variable

```
/*Merge dataset: parameter est, sid, cell into temp
dataset=combine**/

libname perm '.' ;
options nocenter nonotes ;
data ship ;
  set perm.ship1 ;

%macro iter(i,varname) ;
proc reg noprint data=ship outest=curve&i ;
  model &varname =time ;
  by cell sid ;
run ;

%mend iter ;
%iter(1,newassis) ;
%iter(2,newms) ;
%iter(3,newscs1) ;
%iter(3,newscs2) ;
%iter(3,newscs3) ;
%iter(4,newiarb) ;
%iter(5,newmu) ;
%iter(6,newmuis) ;
%iter(7,newnaf) ;
%iter(8,newiwb) ;

data perm.combine ;
  merge curve1(keep=cell sid intercep time
               rename=(intercep=newassi0 time=newassi1))
        curve2(keep=cell sid intercep time
               rename=(intercep=newms0 time=newms1))
        curve3(keep=cell sid intercep time
               rename=(intercep=newscs10 time=newscs11))
        curve4(keep=cell sid intercep time
               rename=(intercep=newscs20 time=newscs21))
        curve5(keep=cell sid intercep time
               rename=(intercep=newscs30 time=newscs31))
```

```
        curve6(keep=cell sid intercep time
              rename=(intercep=newiarb0 time=newiarb1))
        curve7(keep=cell sid intercep time
              rename=(intercep=newmu0 time=newmu1))
        curve8(keep=cell sid intercep time
              rename=(intercep=newmuis0 time=newmuis1))
        curve9(keep=cell sid intercep time
              rename=(intercep=newnaf0 time=newnaf1))
        curve10(keep=cell sid intercep time
              rename=(intercep=newiwb0 time=newiwb1))
by cell sid ;
proc print data=perm.combine ;

proc glm ;
  class cell ;
  model newmu0 newassi0 newscs11 newscs21 newscs31 newiarb1
        newmuis1 newnaf1 newiwb1 = cell ;
  means cell ;

proc glm ;
  class cell ;
  model newscs11 newscs21 newscs31 newiarb1 newmuis1 newnaf1
        newiwb1 = newms0 ;
  means cell ;

proc glm ;
  class cell ;
  model newscs11 newscs21 newscs31 newiarb1 newmuis1 newnaf1
        newiwb1 = newassi0 ;

proc means mean var std max min t prt maxdec=2 ;
 class cell ;
 where _depvar_^='' ;
 by _depvar_ ;
 var intercept time ;
 output ;*/
```

```
/* exporting sas dataset to SPSS portable dataset for
further analysis*/

data perm.expdata1 ;
set perm.combine ;
file 'expdata1' linesize=250;
lrecl=250 ;
put (cell sid newassi0 newassi1 newms0 newms1 newscs10
newscs11 newscs20 newscs21 newscs30 newscs31 newiarb0
newiarb1 newmu0 newmu1 newmuis0 newmuis1 newnaf0 newnaf1
newiwb0 newiwb1) (10.5);
run;
```

SAS Program For Reading In Permanent SAS Dataset As Temporary File, Then Run Individual Regressions

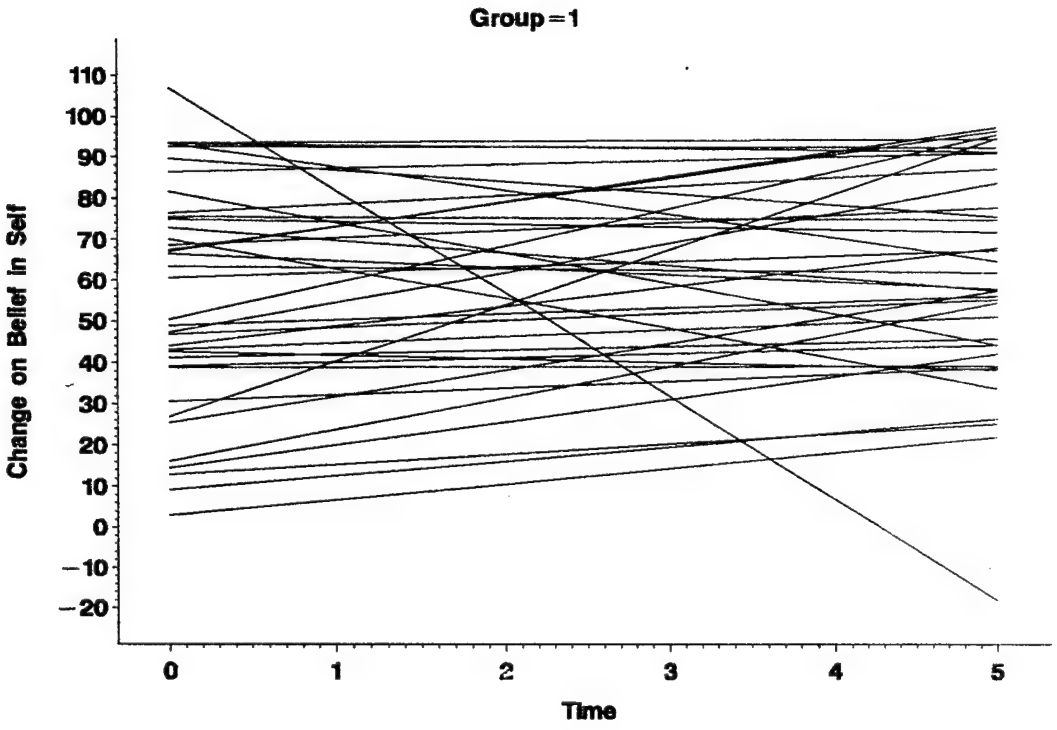
```
/*Merge dataset: parameter est, sid, cell into temp
dataset=combine**/

libname perm '.' ;
options nocenter nonotes ;
data ship ;
  set perm.ship1 ;

%macro iter(i,varname) ;
proc reg noprint data=ship outest=curve&i ;
  model &varname =time ;
  by cell sid ;
run ;
%mend iter ;
%iter(1,newassis) ;
%iter(2,newms) ;
%iter(3,newscs1) ;
%iter(3,newscs2) ;
%iter(3,newscs3) ;
%iter(4,newiarb) ;
%iter(5,newmu) ;
%iter(6,newmuis) ;
%iter(7,newnaf) ;
%iter(8,newiwb) ;

data perm.combine ;
  merge curve1(keep=cell sid intercep time
               rename=(intercep=newassi0 time=newassi1))
        curve2(keep=cell sid intercep time
               rename=(intercep=newms0 time=newms1))
        curve3(keep=cell sid intercep time
               rename=(intercep=newscs10 time=newscs11))
        curve4(keep=cell sid intercep time
               rename=(intercep=newscs20 time=newscs21))
        curve5(keep=cell sid intercep time
               rename=(intercep=newscs30 time=newscs31))
        curve6(keep=cell sid intercep time
               rename=(intercep=newiarb0 time=newiarb1))
```

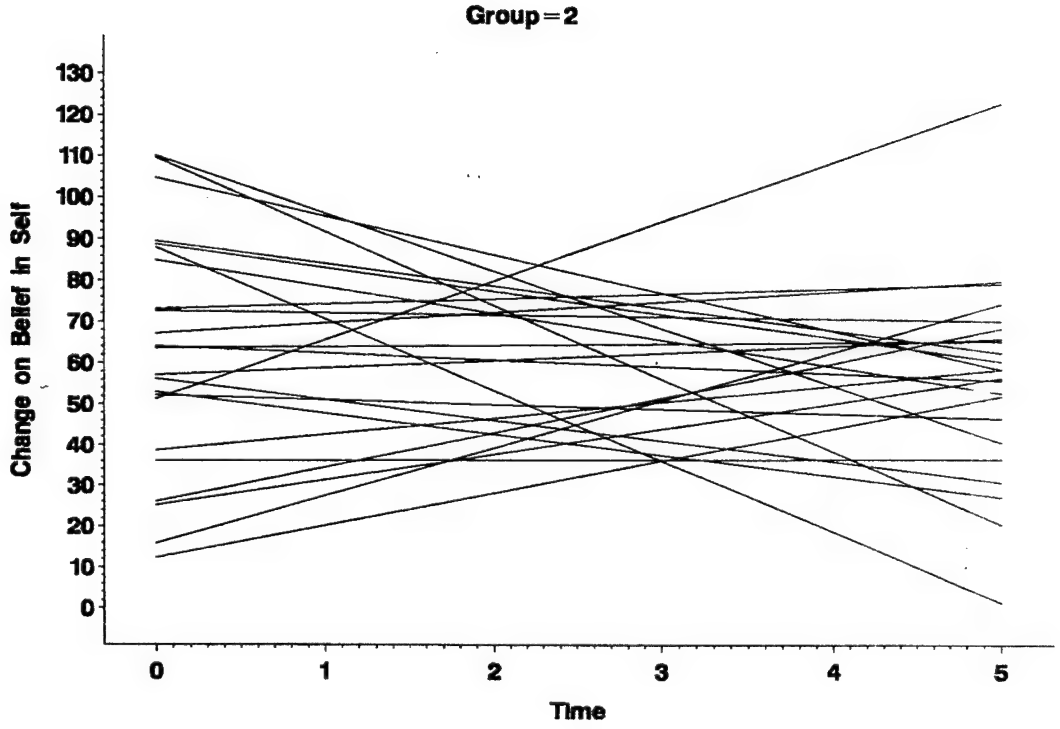
```
        curve7(keep=cell sid intercep time
              rename=(intercep=newmu0 time=newmu1))
        curve8(keep=cell sid intercep time
              rename=(intercep=newmuis0 time=newmuis1))
        curve9(keep=cell sid intercep time
              rename=(intercep=newnaf0 time=newnaf1))
        curve10(keep=cell sid intercep time
              rename=(intercep=newiwb0 time=newiwb1))
by cell sid ;
proc print data=perm.combine ;
```

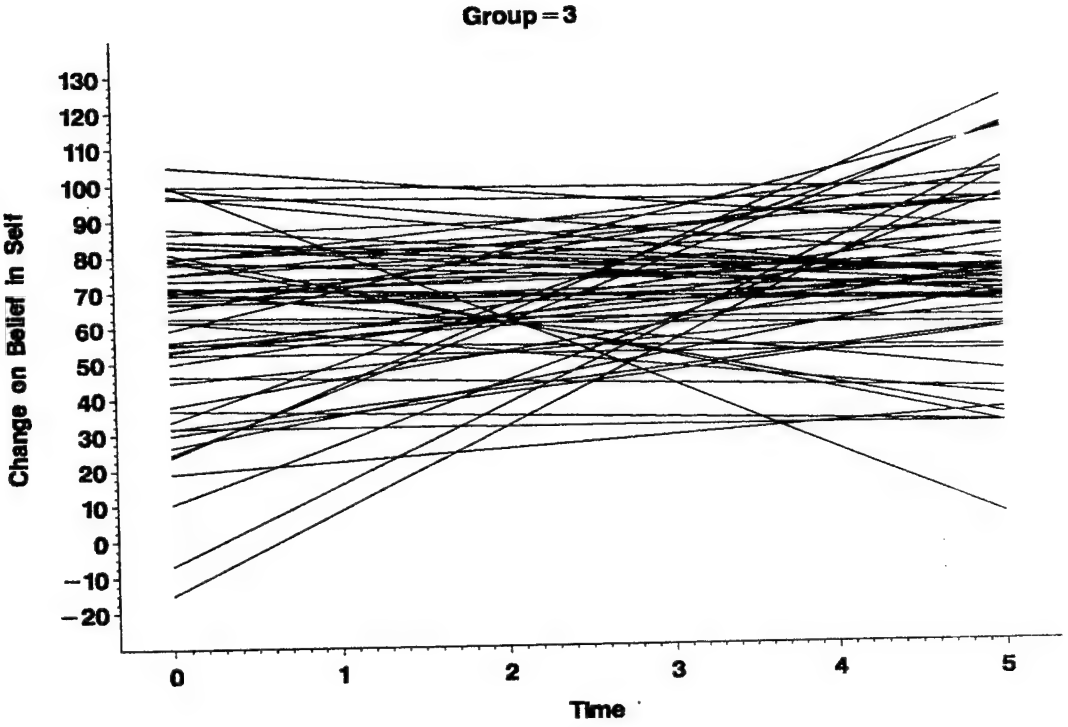
Appendix F

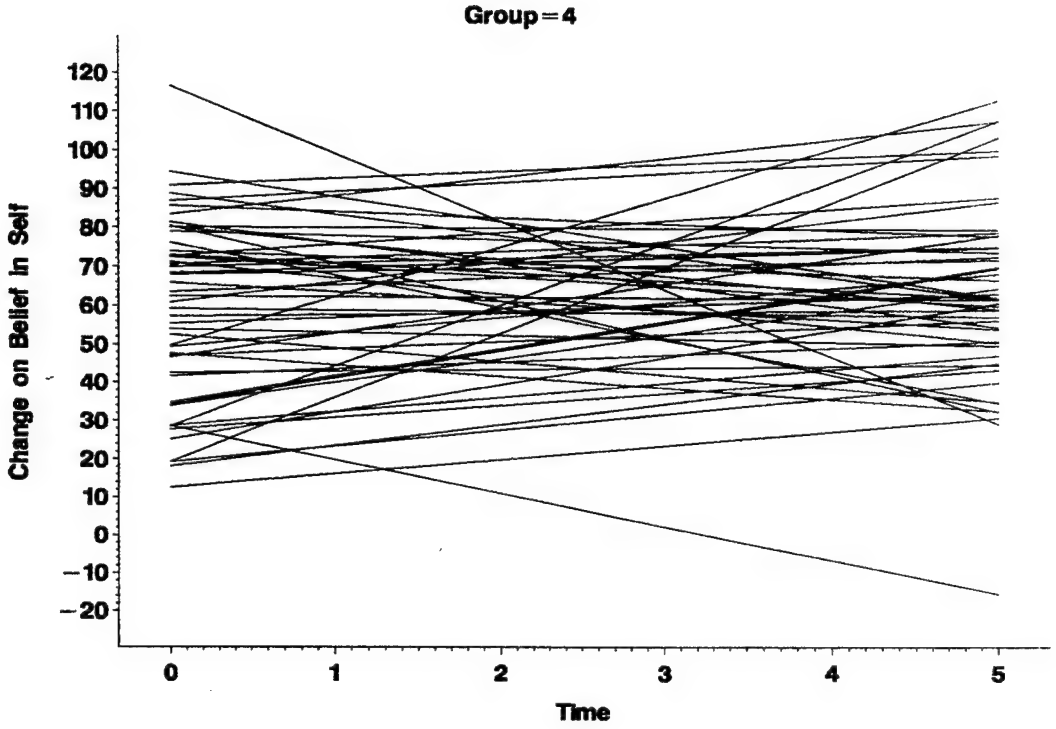
1. Plottings of Individual Change per Outcome Variable by Treatment Groups: SHIS, SHC, UM, SHIS/UM, and SHC/UM

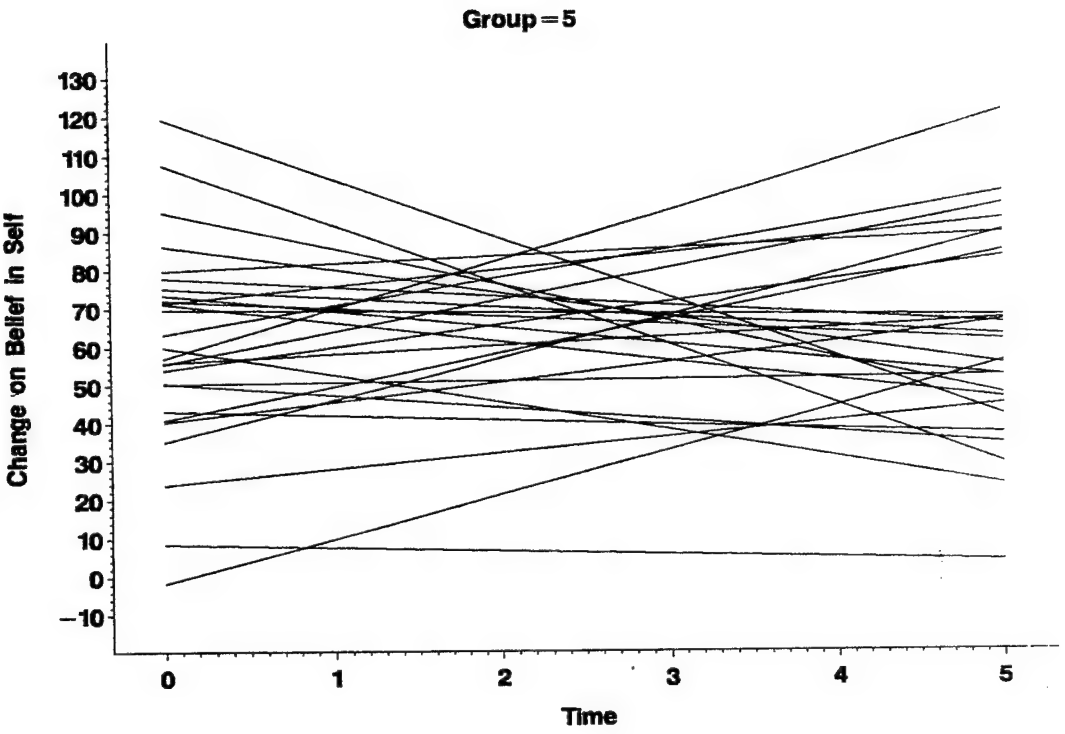
2.Plottings of Change in Outcomes at Group Level (SHC/SHIS, UM, SHIS+UM/SHC+UM, and Natural Learning Condition/Control Group)

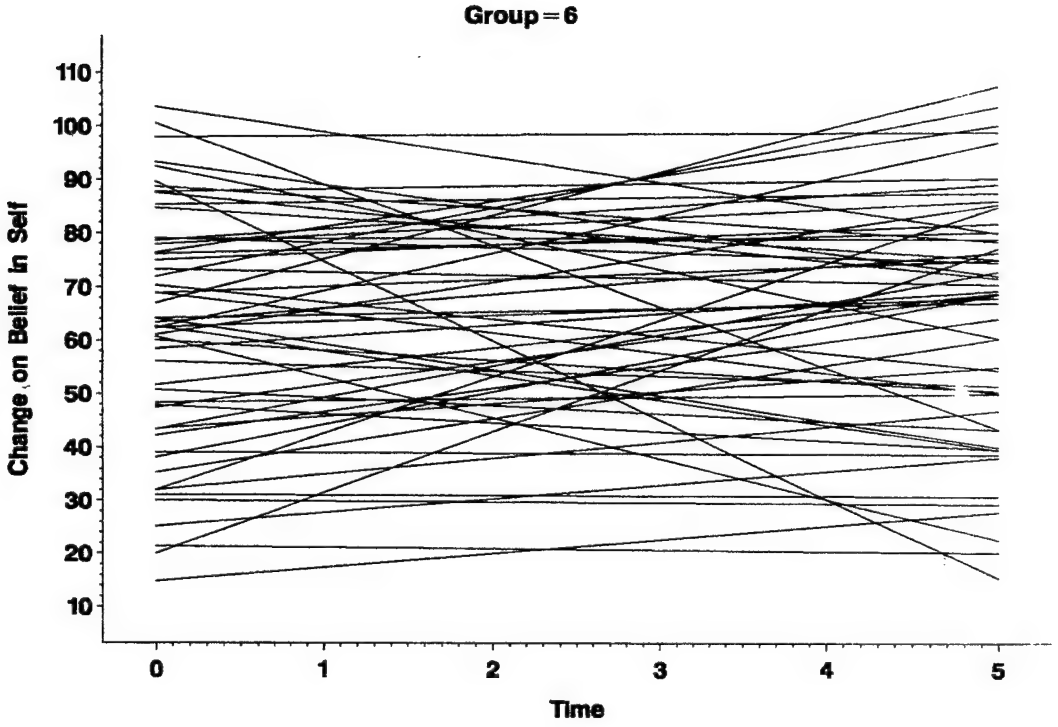

Group=1
Change on Belief in Self
110
100
90
80
70
60
50
40
30
20
10
0
−10
−20
0
1
2
3
4
5
Time

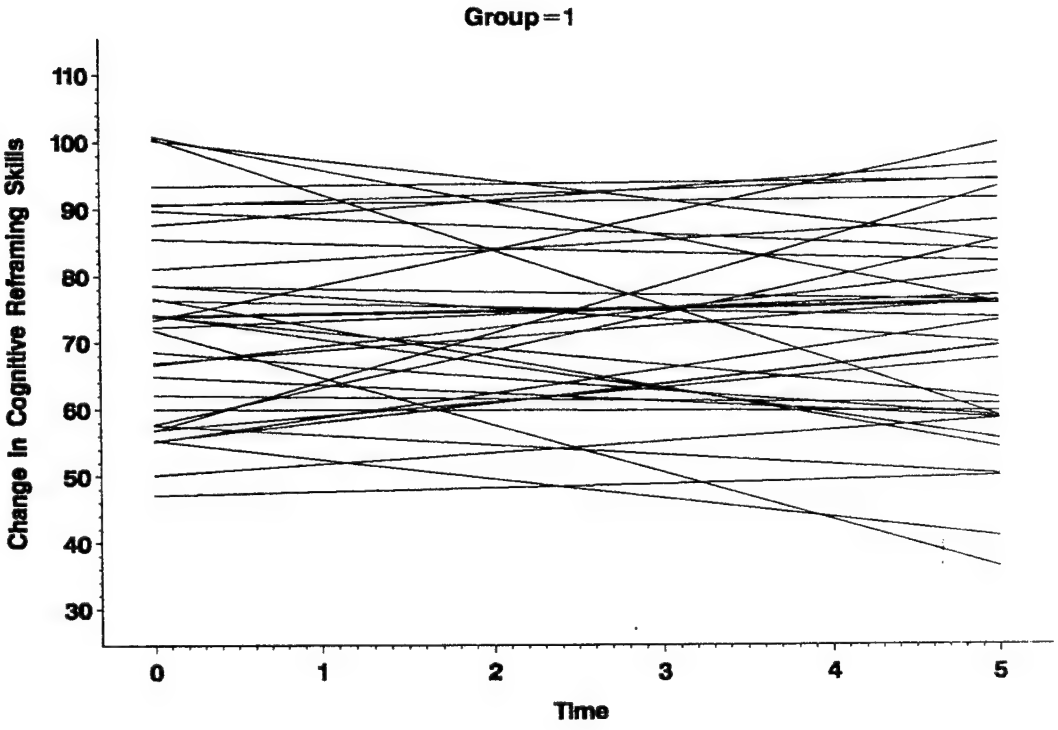

Group=2
Change on Belief in Self
130
120
110
100
90
80
70
60
50
40
30
20
10
0
0
1
2
3
4
5
Time

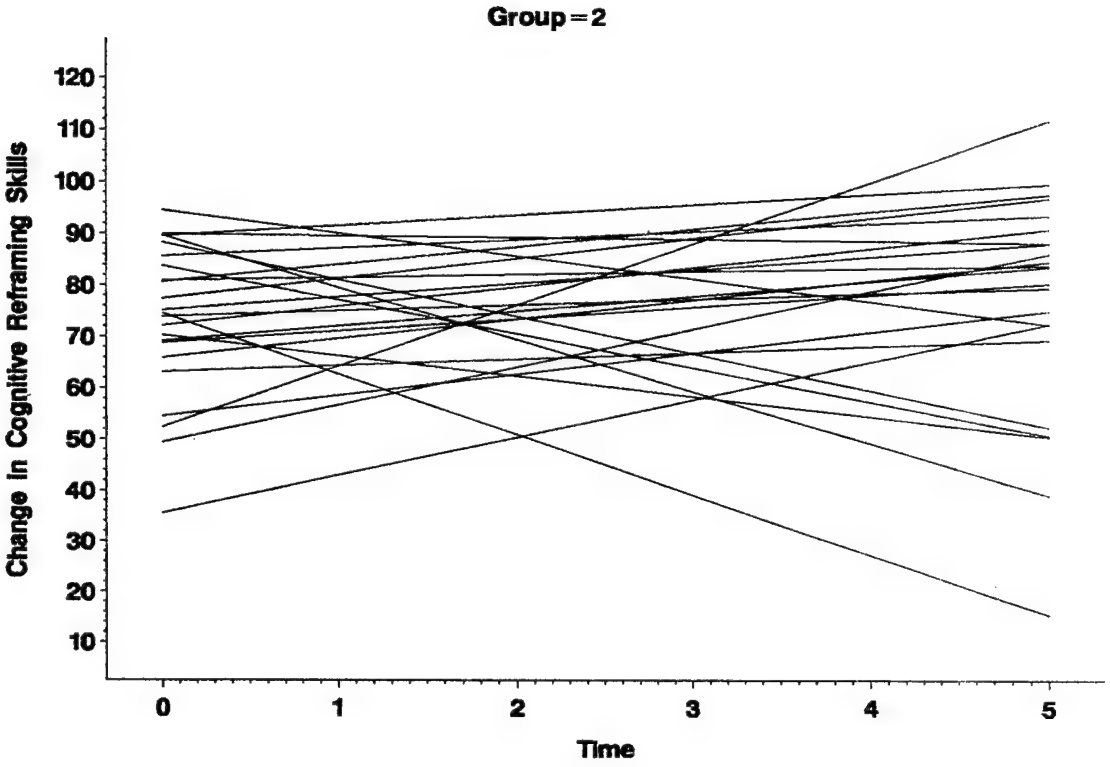

Group = 3
Change on Belief in Self
130
120
110
100
90
80
70
60
50
40
30
20
10
0
−10
−20
0
1
2
3
4
5
Time

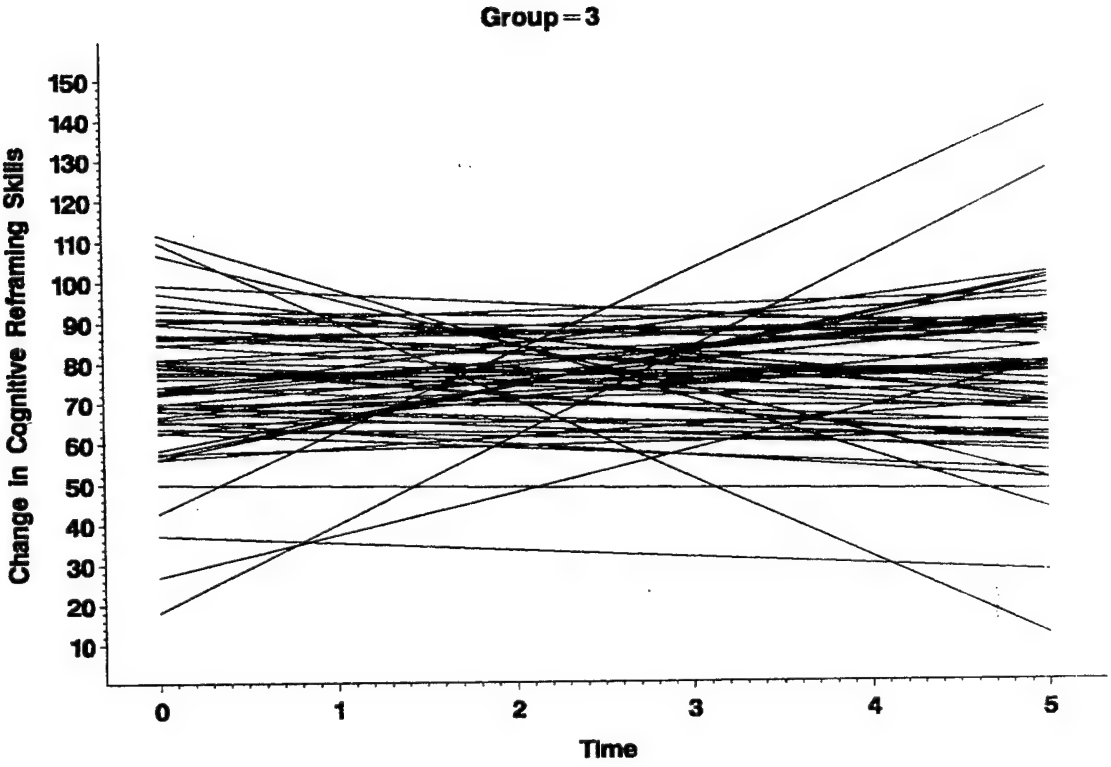

Group=4
Change on Belief in Self
120
110
100
90
80
70
60
50
40
30
20
10
0
−10
−20
0
1
2
3
4
5
Time

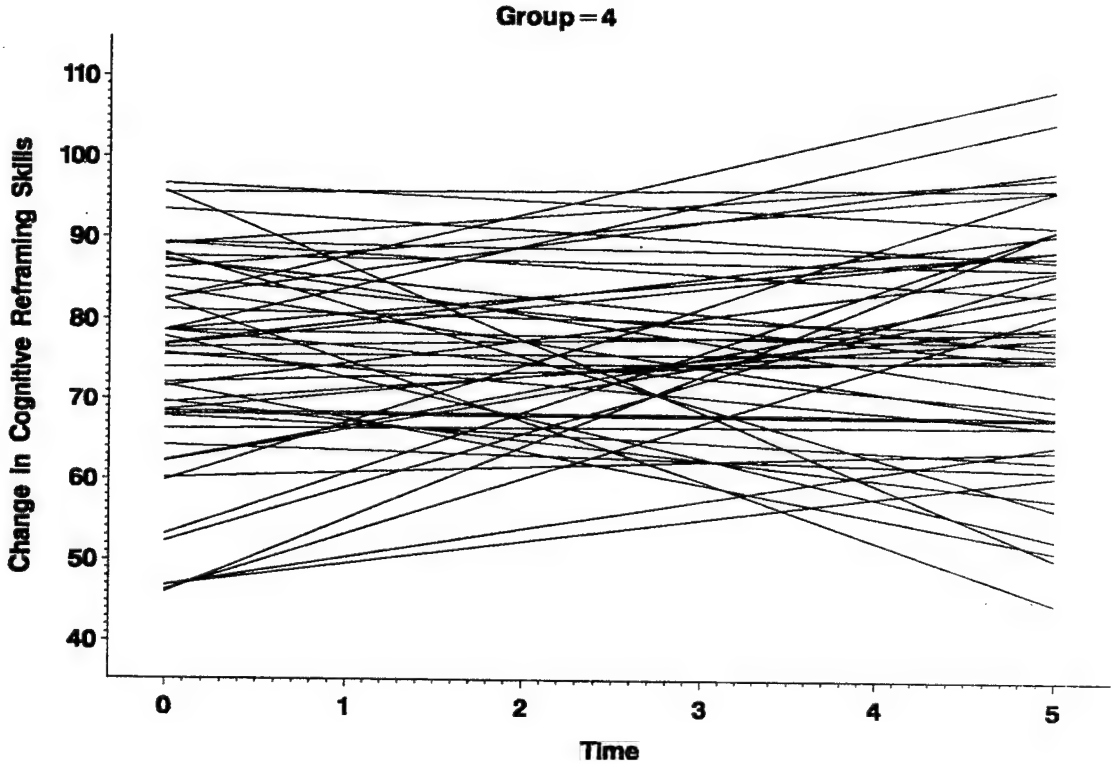

Group = 5
Change on Belief in Self
130
120
110
100
90
80
70
60
50
40
30
20
10
0
−10
0
1
2
3
4
5
Time

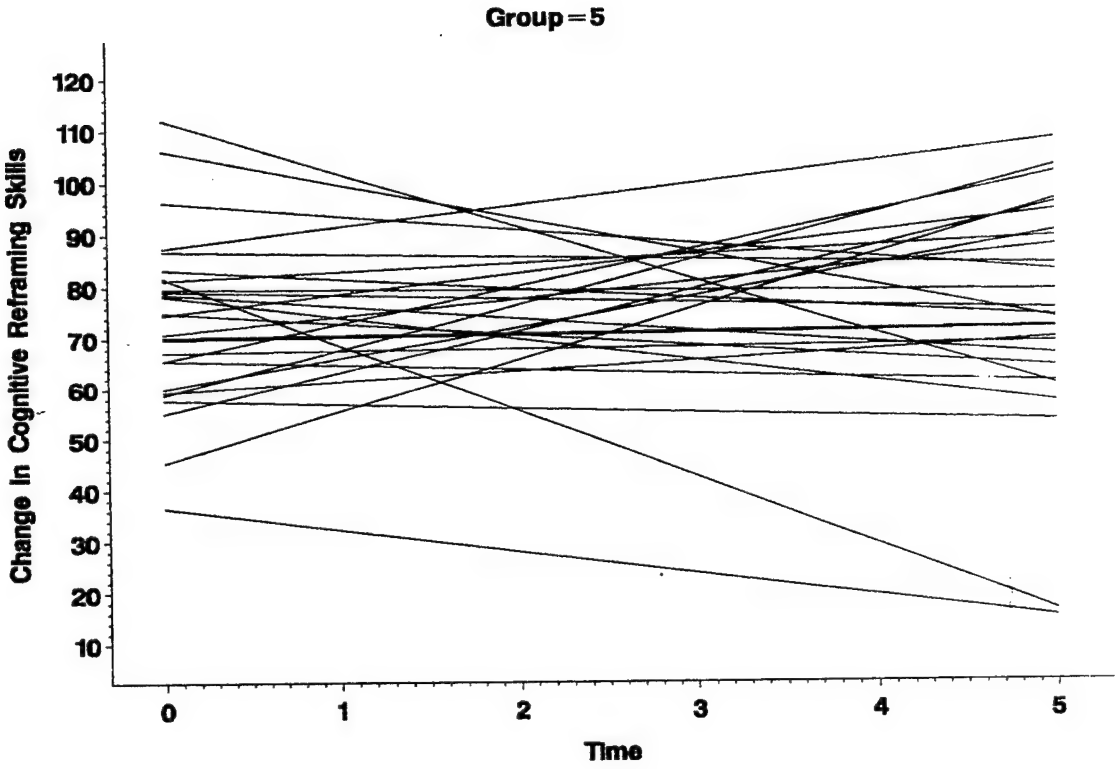

Group = 6
Change on Belief in Self
110
100
90
80
70
60
50
40
30
20
10
0
1
2
3
4
5
Time

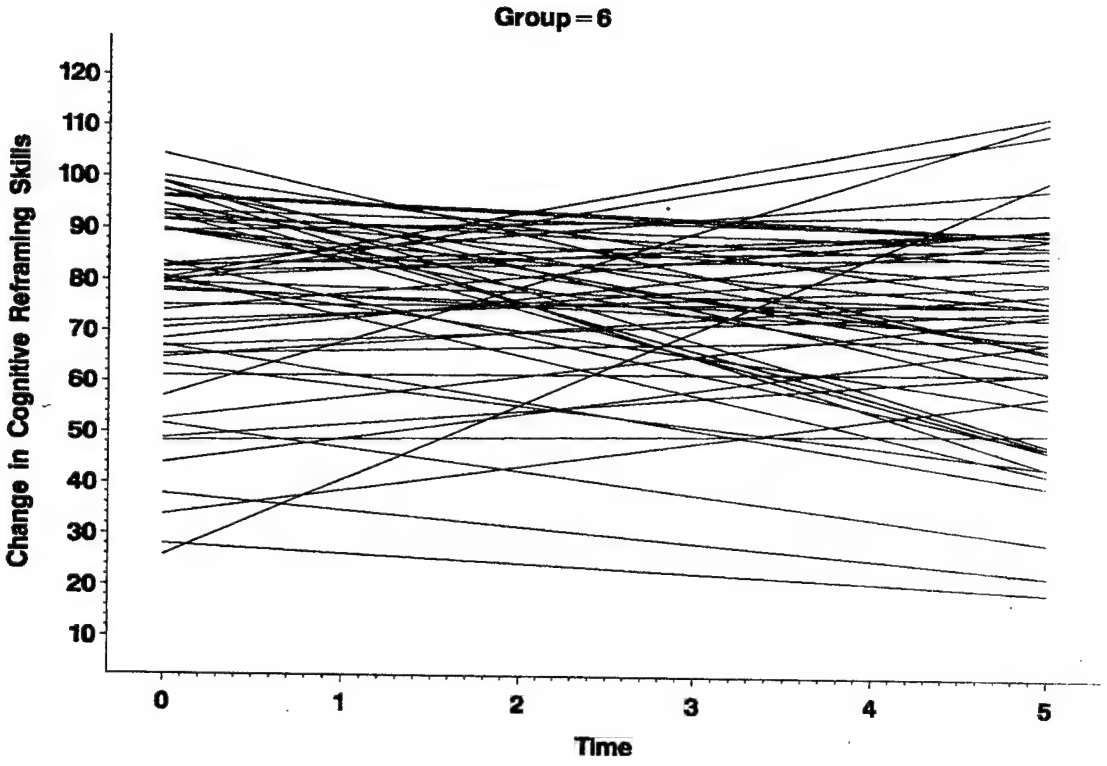

Group=1
Change In Cognitive Reframing Skills
110
100
90
80
70
60
50
40
30
0
1
2
3
4
5
Time

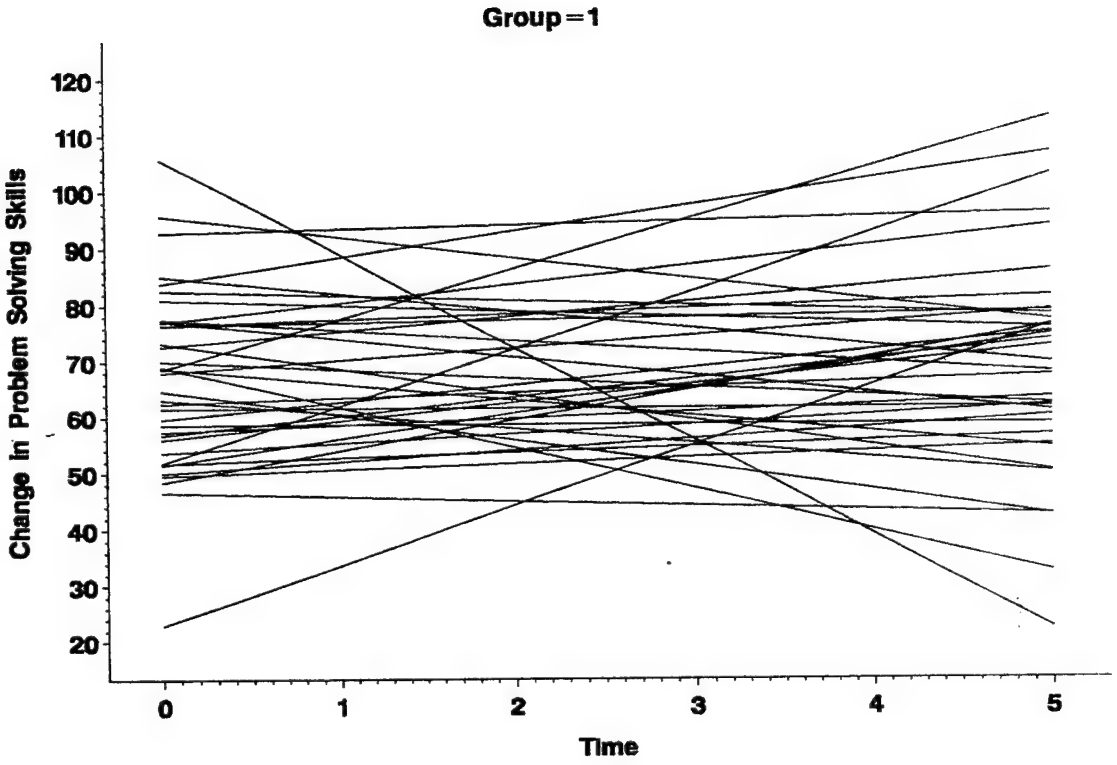

Group=2
Change in Cognitive Reframing Skills
120
110
100
90
80
70
60
50
40
30
20
10
0
1
2
3
4
5
Time

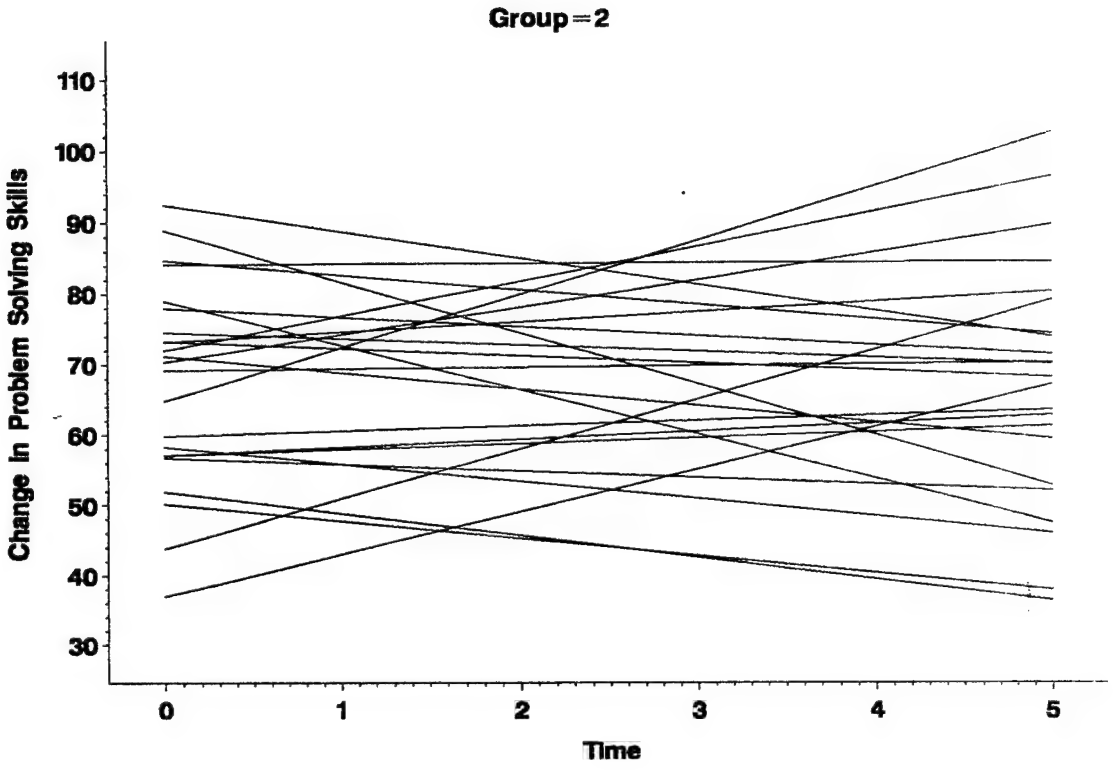

Group=3
Change in Cognitive Reframing Skills
150
140
130
120
110
100
90
80
70
60
50
40
30
20
10
0
1
2
3
4
5
Time

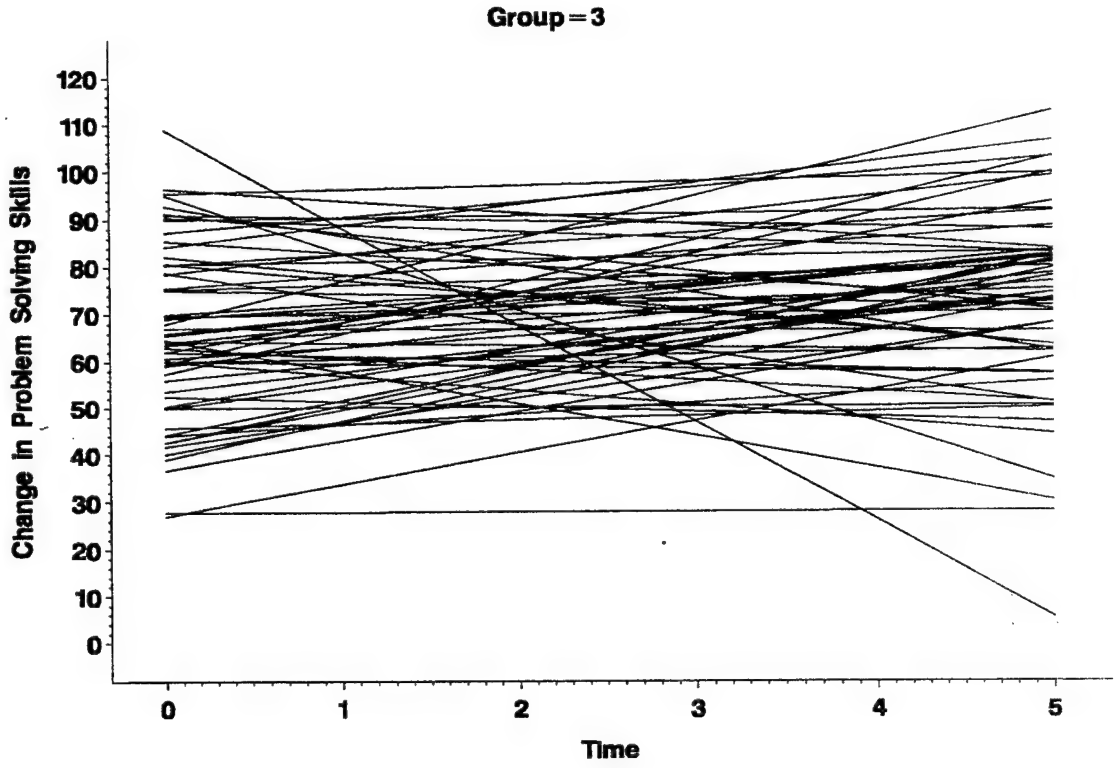

Group = 4
Change in Cognitive Reframing Skills
110
100
90
80
70
60
50
40
0
1
2
3
4
5
Time

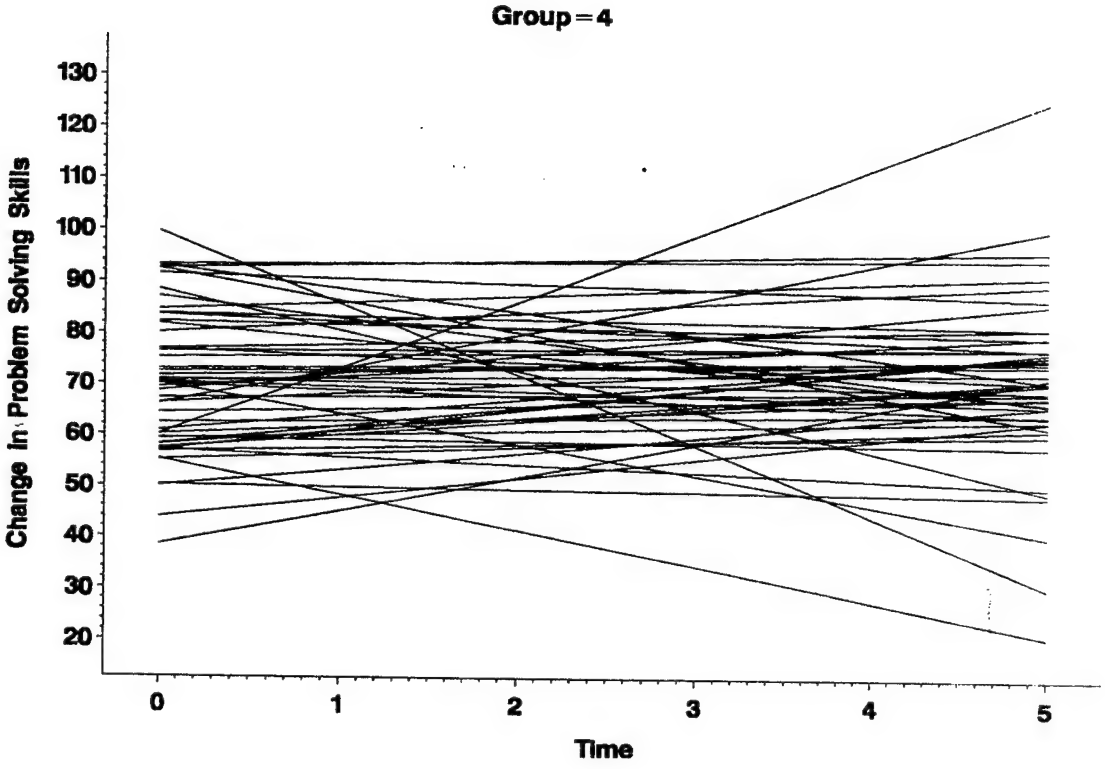

Group=5
Change In Cognitive Reframing Skills
120
110
100
90
80
70
60
50
40
30
20
10
0
1
2
3
4
5
Time

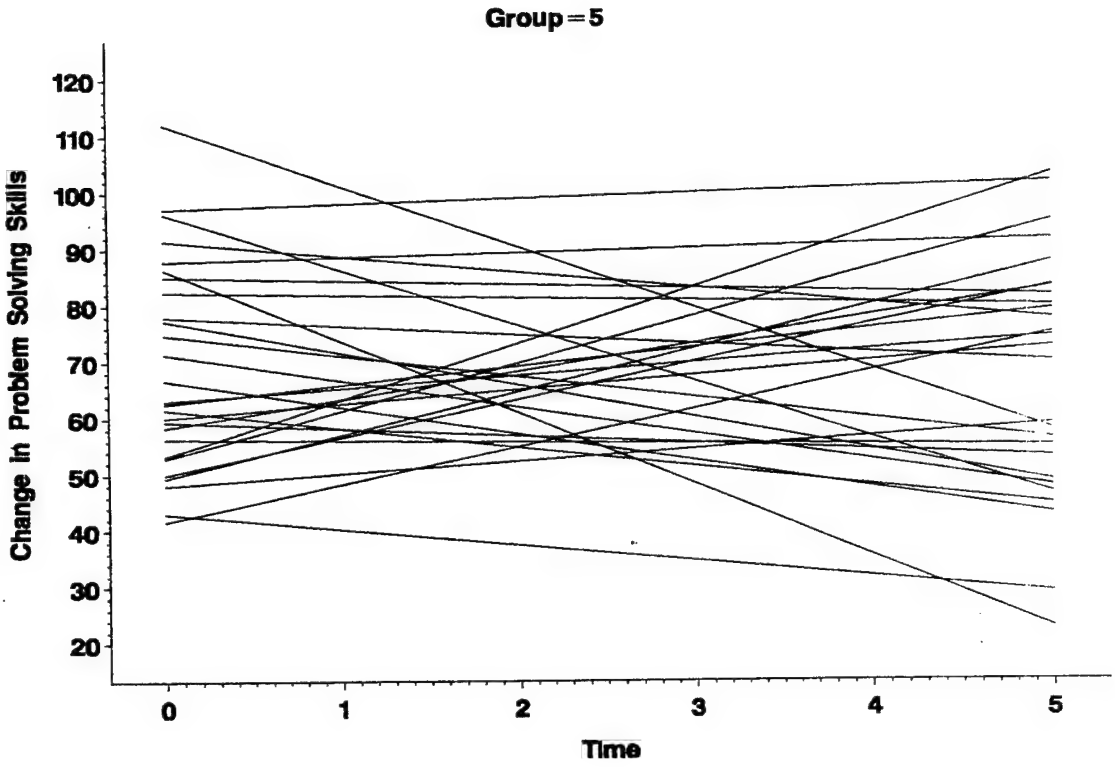

Group=6
Change in Cognitive Reframing Skills
120
110
100
90
80
70
60
50
40
30
20
10
0
1
2
3
4
5
Time

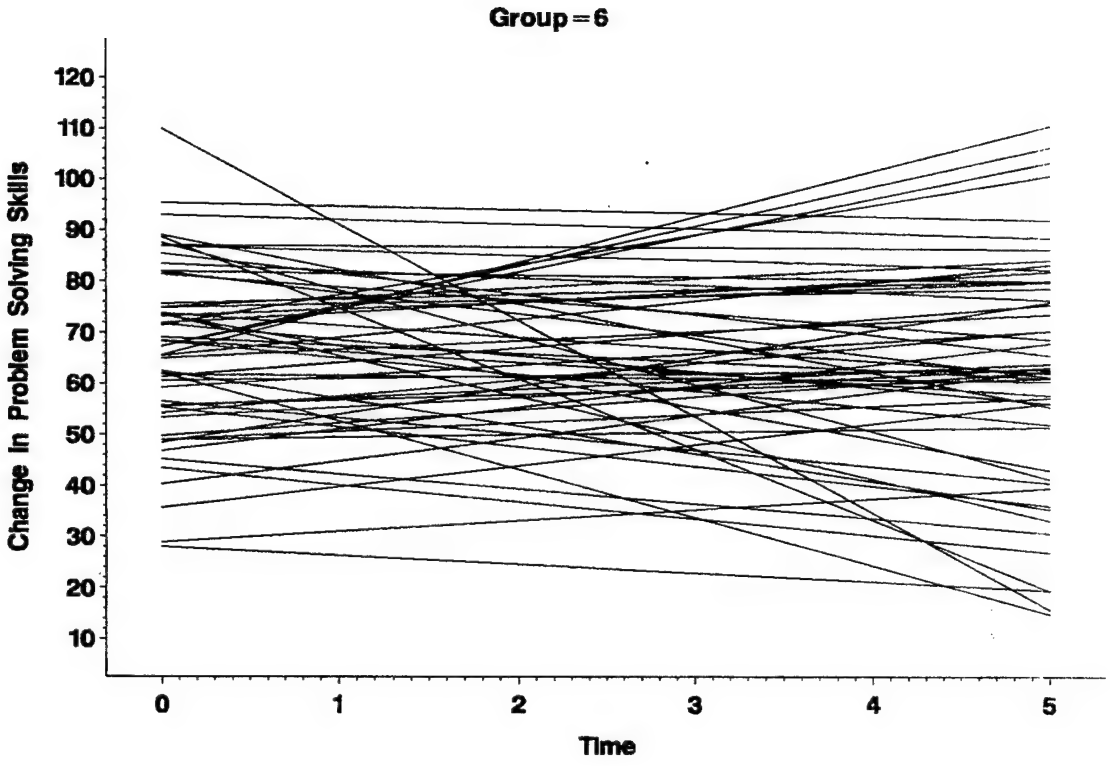

Group=1
Change in Problem Solving Skills
120
110
100
90
80
70
60
50
40
30
20
0
1
2
3
4
5
Time

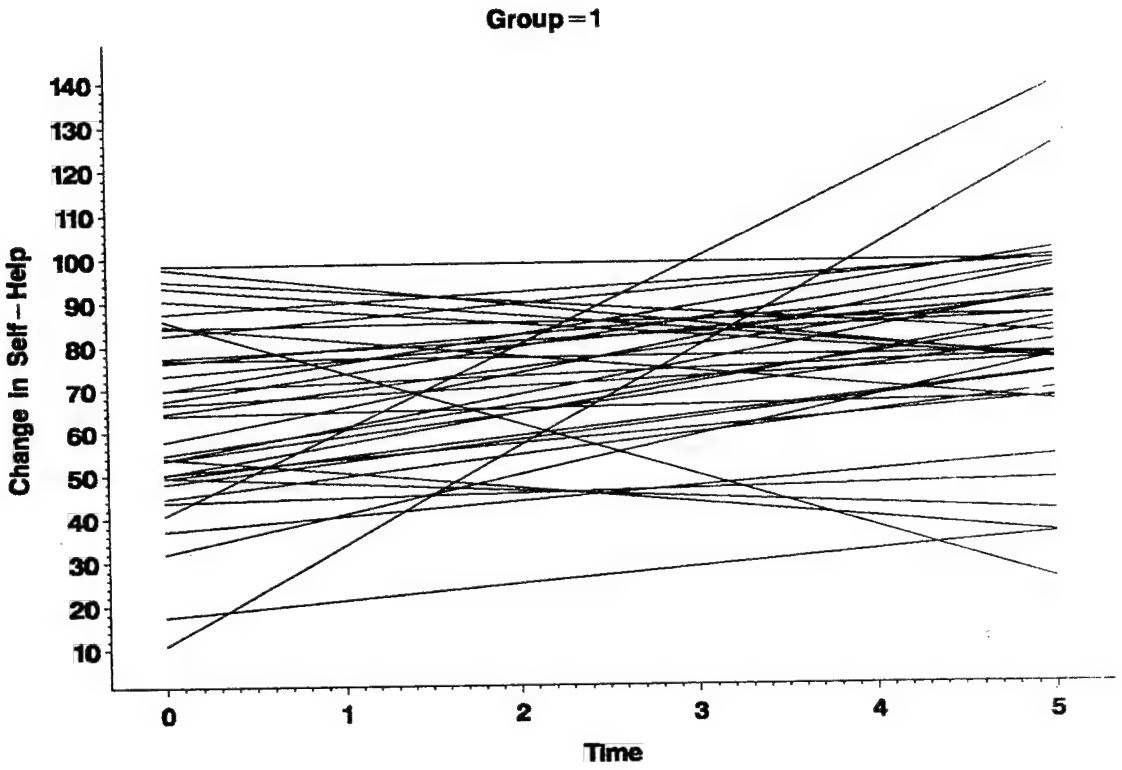

Group=2
Change In Problem Solving Skills
110
100
90
80
70
60
50
40
30
0
1
2
3
4
5
Time

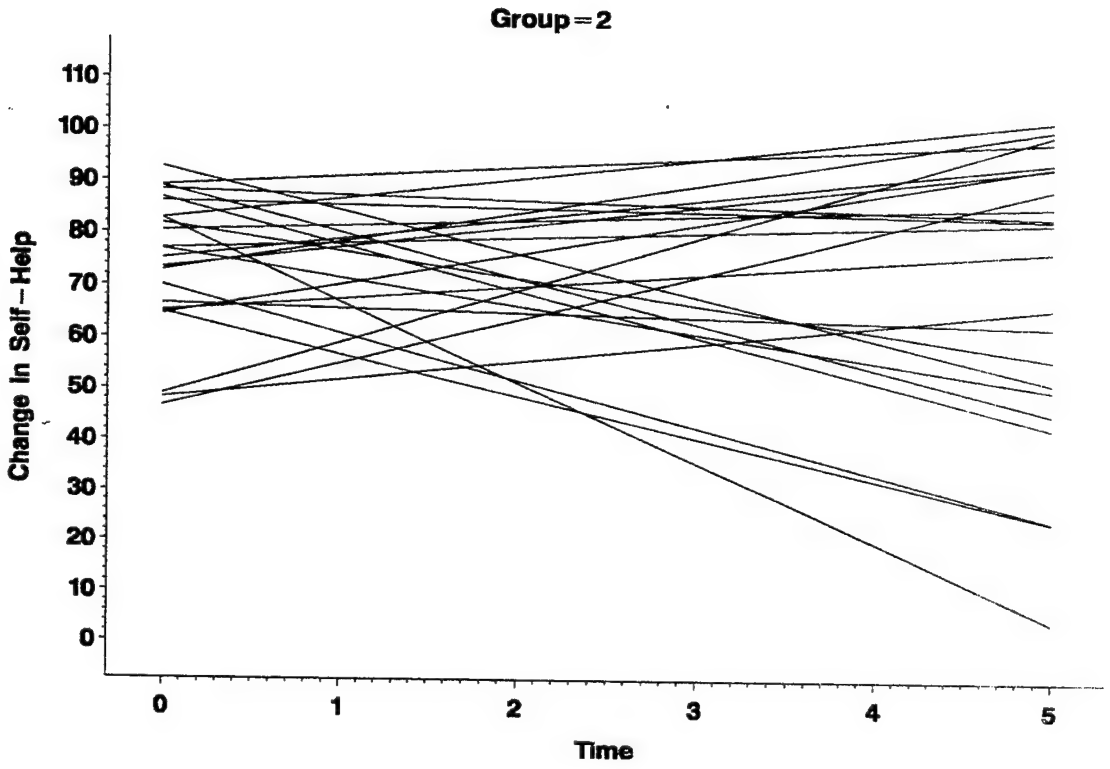

Group = 3
Change in Problem Solving Skills
120
110
100
90
80
70
60
50
40
30
20
10
0
0
1
2
3
4
5
Time

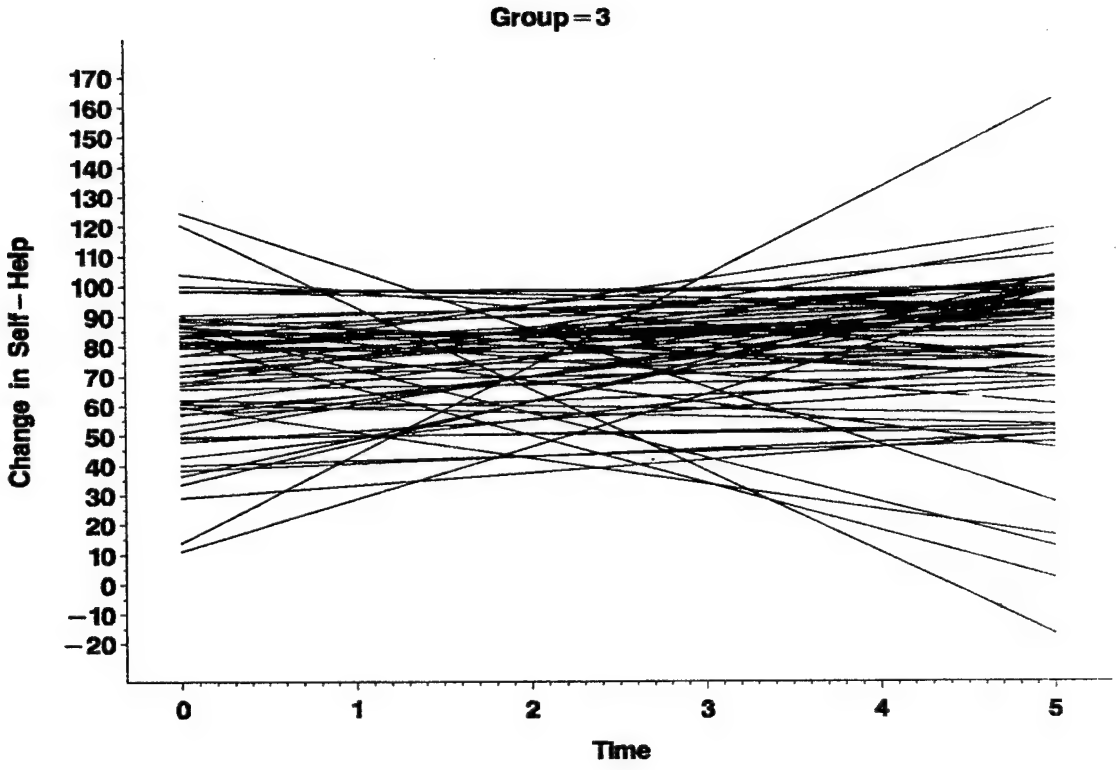

Group = 4
Change In Problem Solving Skills
130
120
110
100
90
80
70
60
50
40
30
20
0
1
2
3
4
5
Time

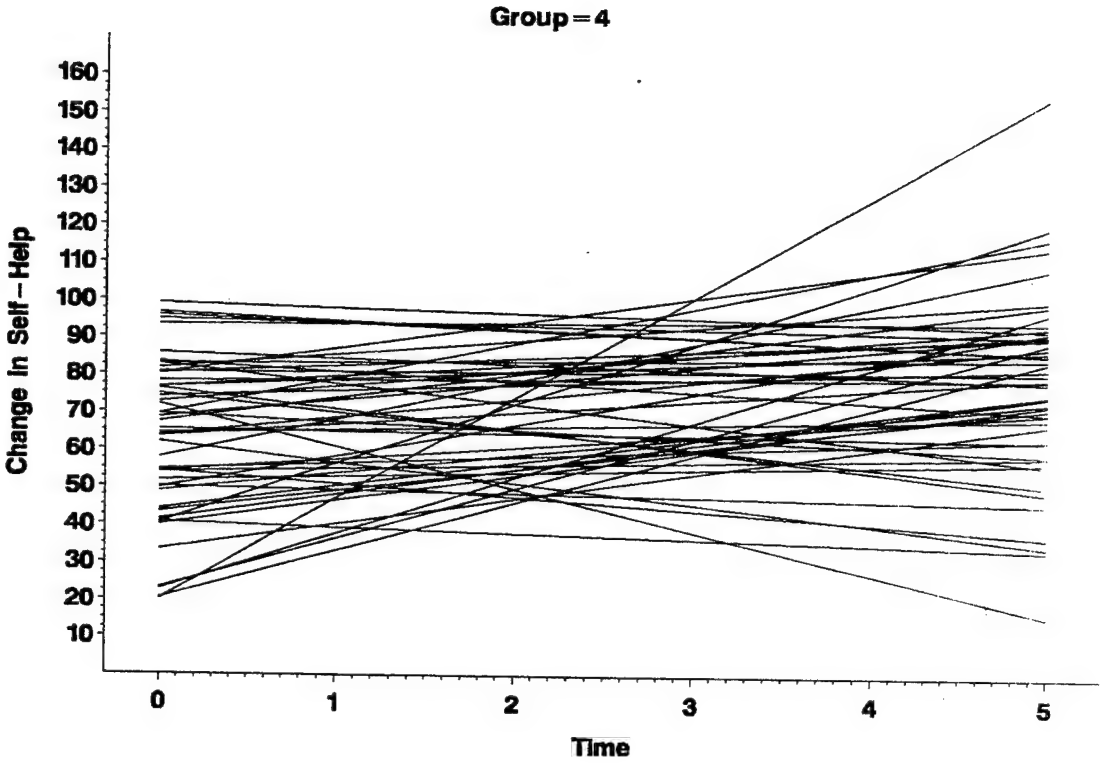

Group=5
Change In Problem Solving Skills
120
110
100
90
80
70
60
50
40
30
20
0
1
2
3
4
5
Time

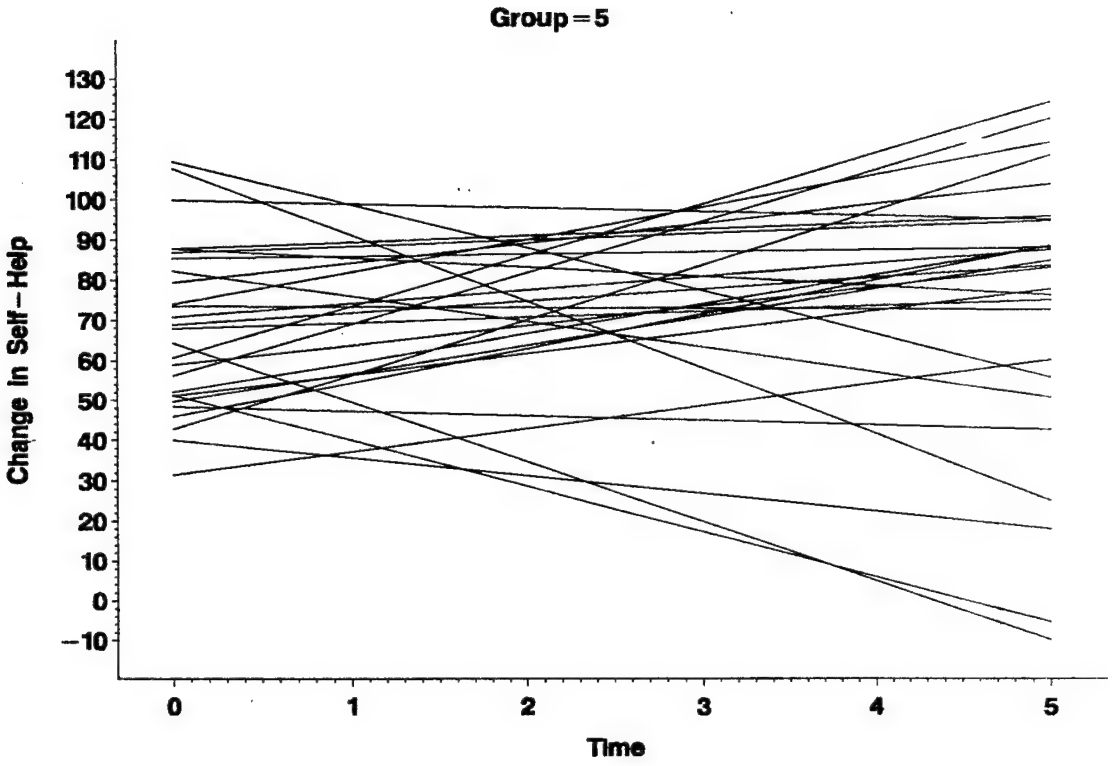

Group = 6
Change In Problem Solving Skills
120
110
100
90
80
70
60
50
40
30
20
10
0
1
2
3
4
5
Time

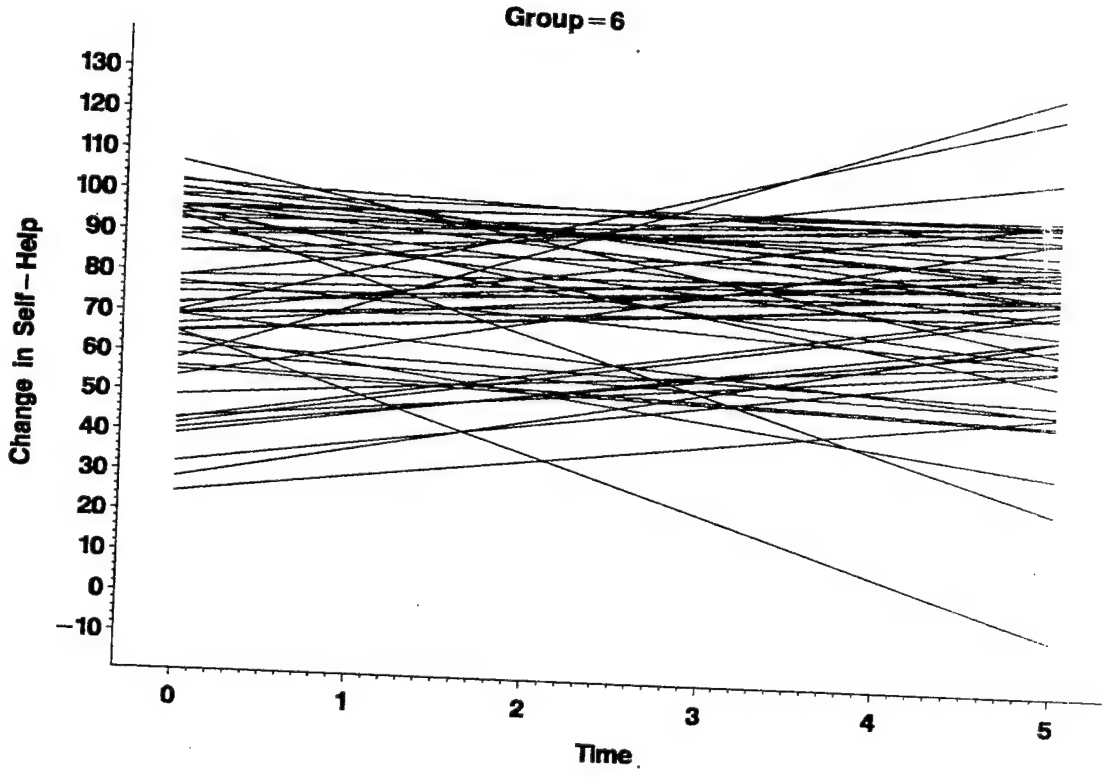

Group=1
Change in Self-Help
140
130
120
110
100
90
80
70
60
50
40
30
20
10
0
1
2
3
4
5
Time


Group=2
Change in Self-Help
110
100
90
80
70
60
50
40
30
20
10
0
0
1
2
3
4
5
Time


Group = 3
Change in Self – Help
170
160
150
140
130
120
110
100
90
80
70
60
50
40
30
20
10
0
−10
−20
0
1
2
3
4
5
Time


Group = 4
Change In Self-Help
160
150
140
130
120
110
100
90
80
70
60
50
40
30
20
10
0
1
2
3
4
5
Time


Group = 5
Change In Self-Help
130
120
110
100
90
80
70
60
50
40
30
20
10
0
−10
0
1
2
3
4
5
Time


Group = 6
Change in Self-Help
130
120
110
100
90
80
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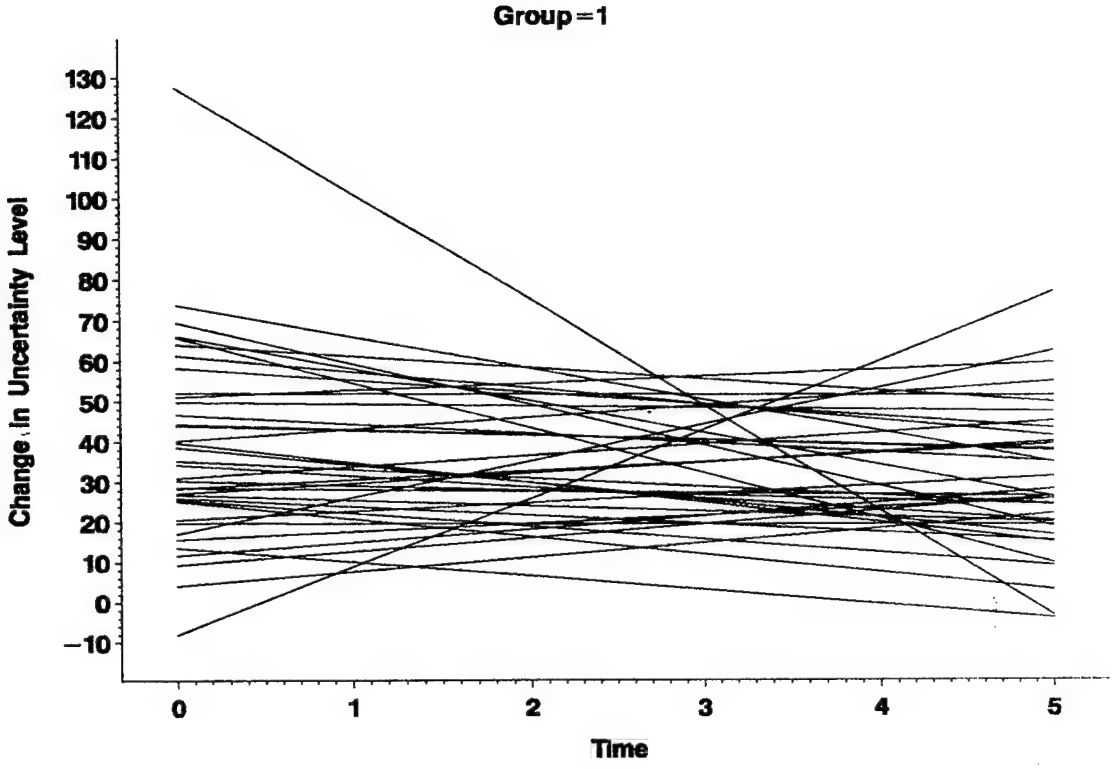
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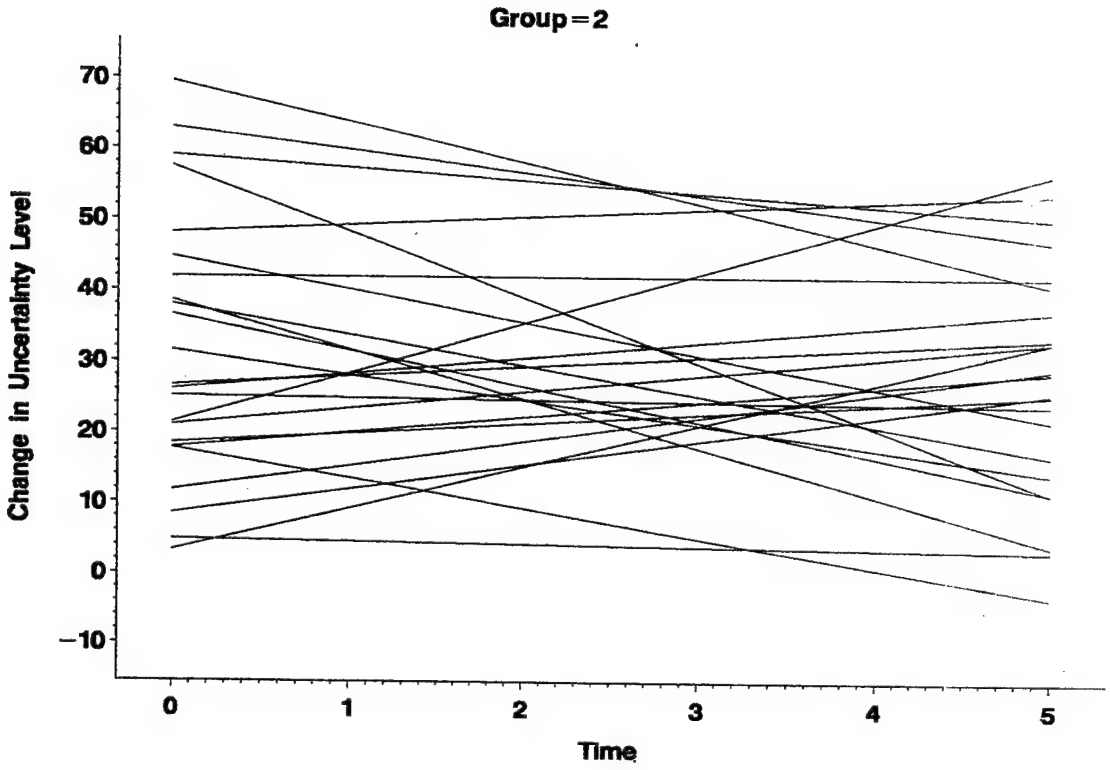
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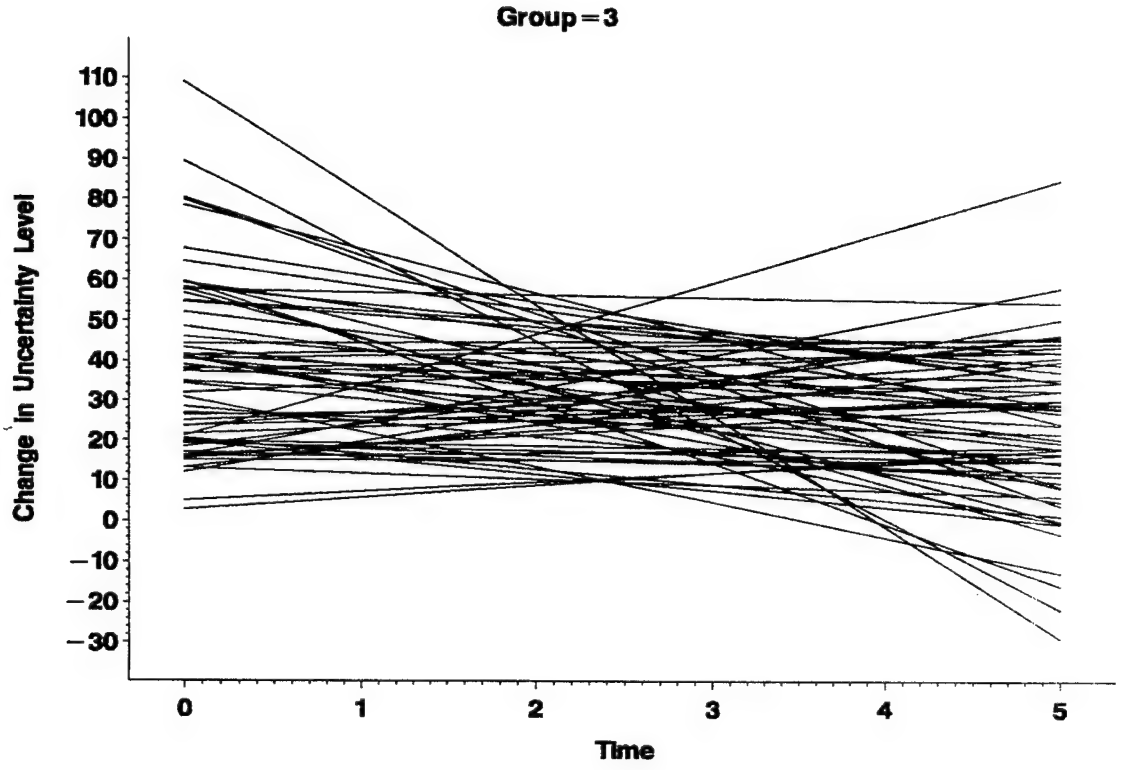
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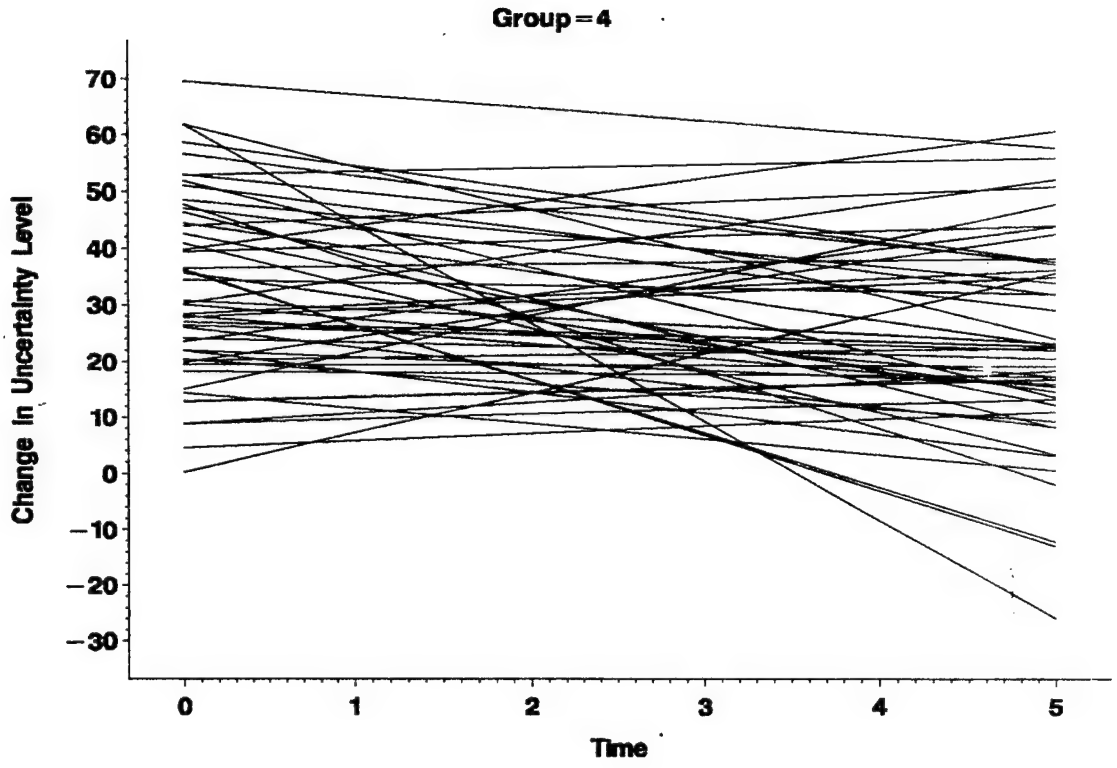
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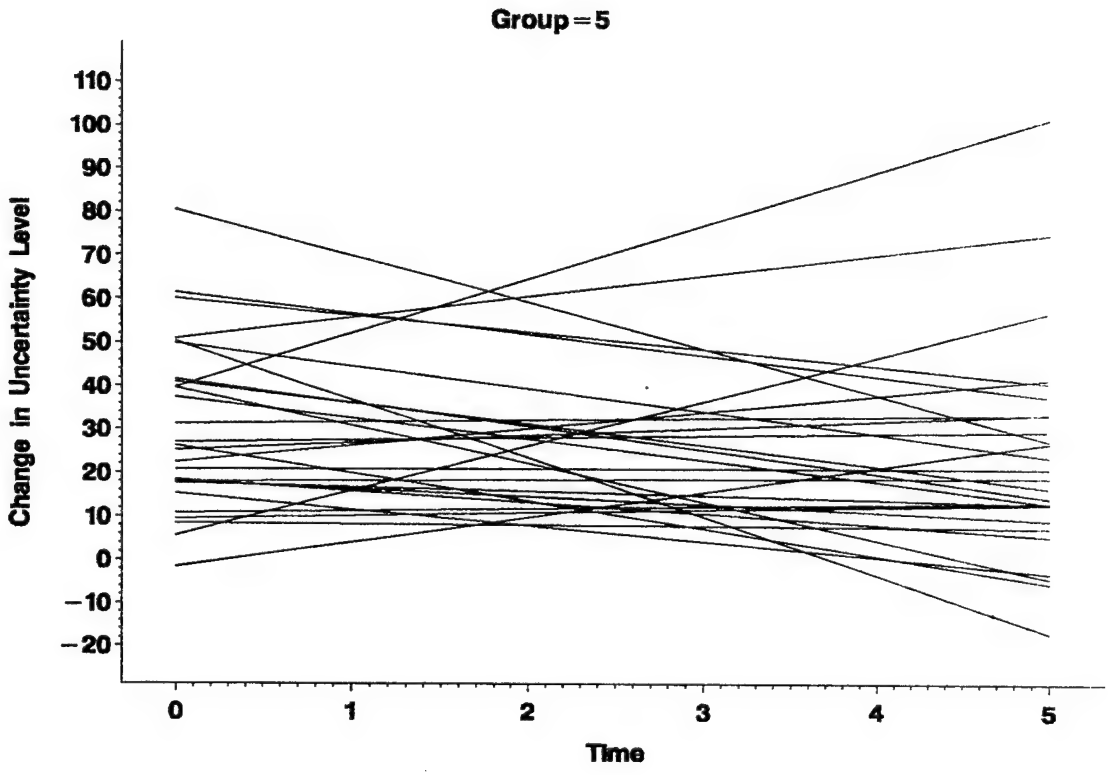
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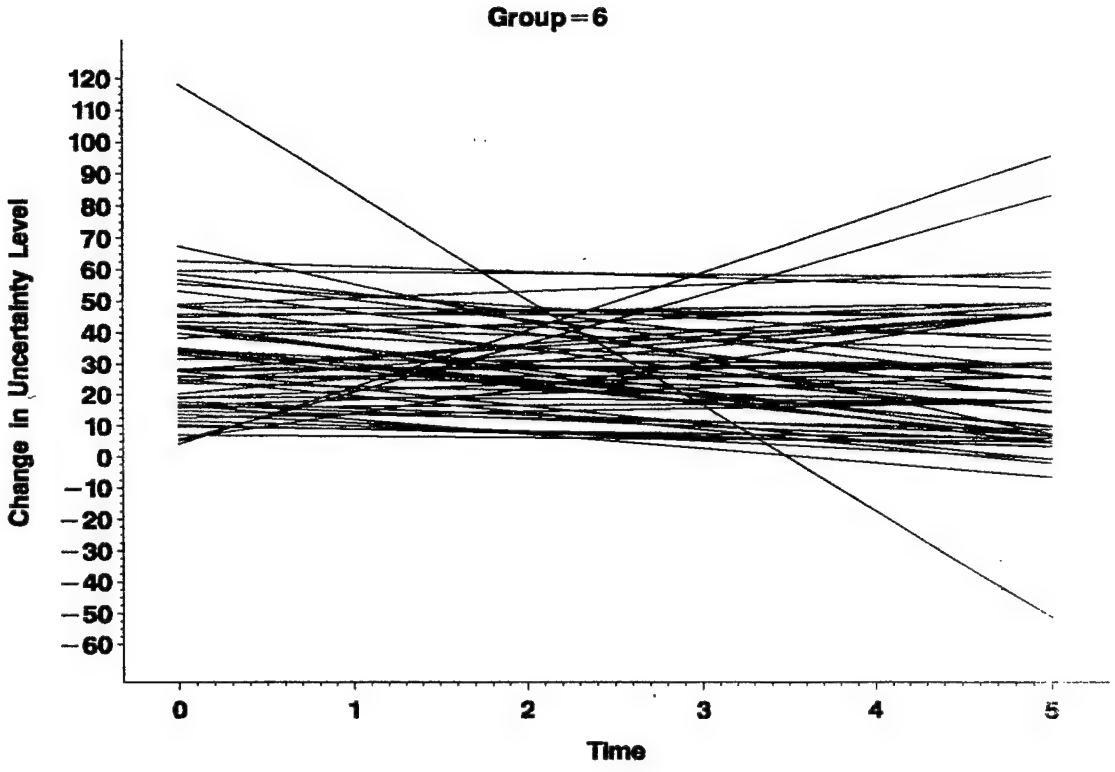
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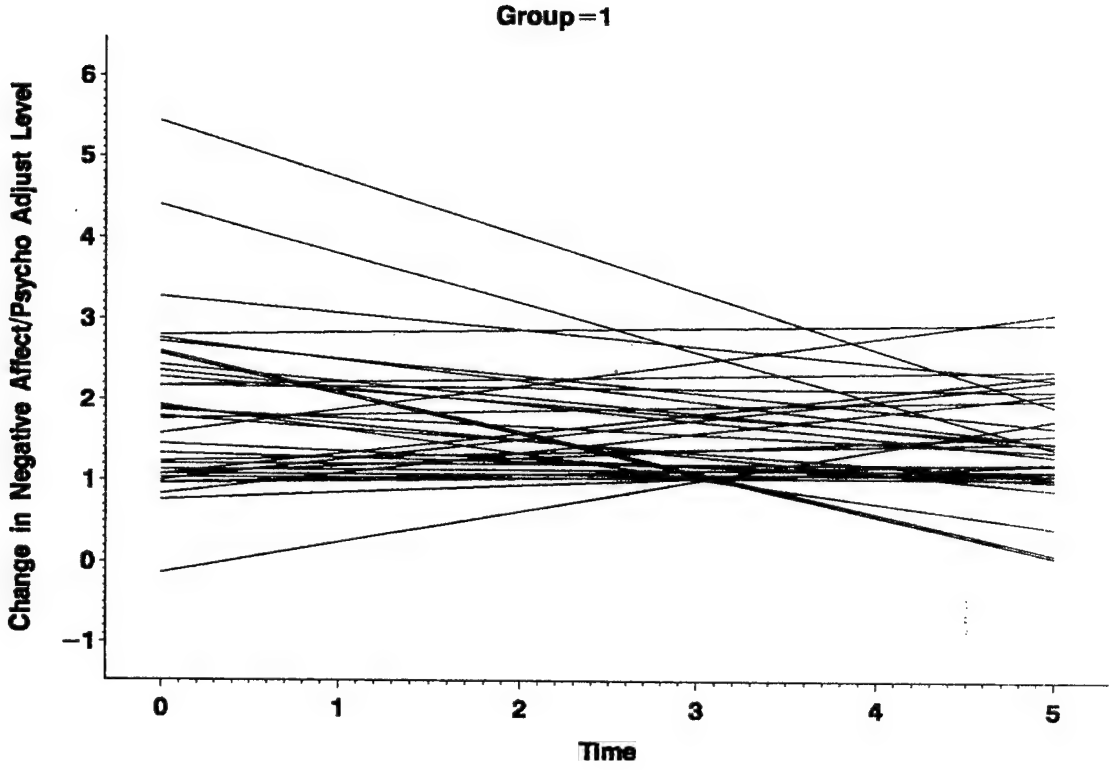
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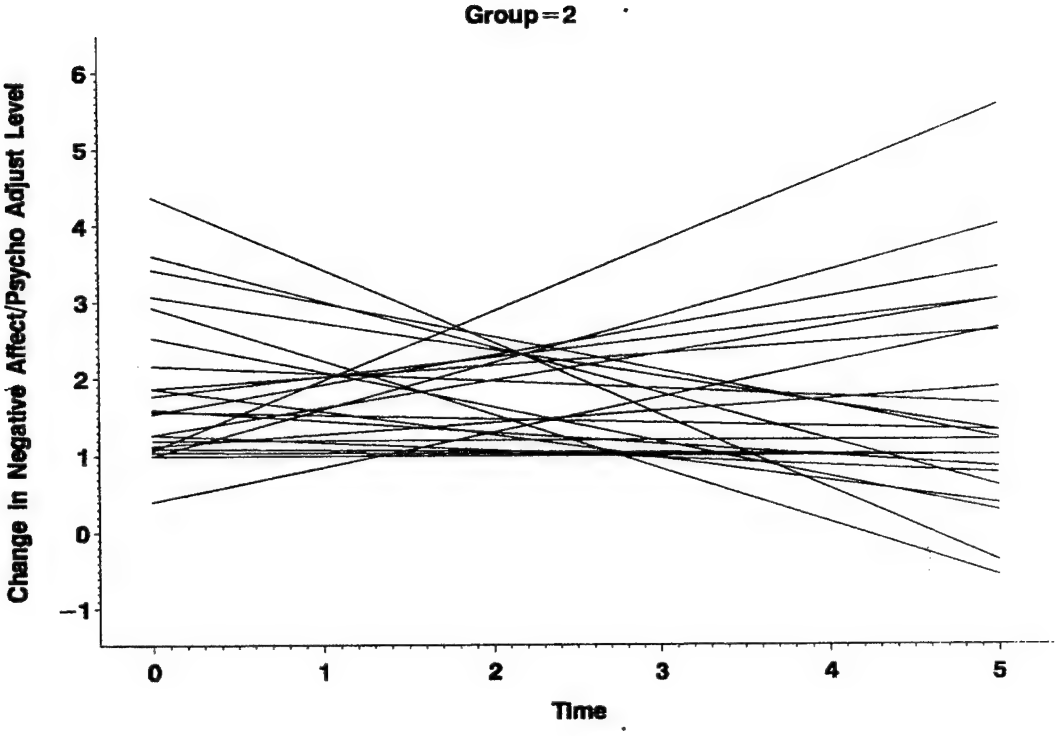
Time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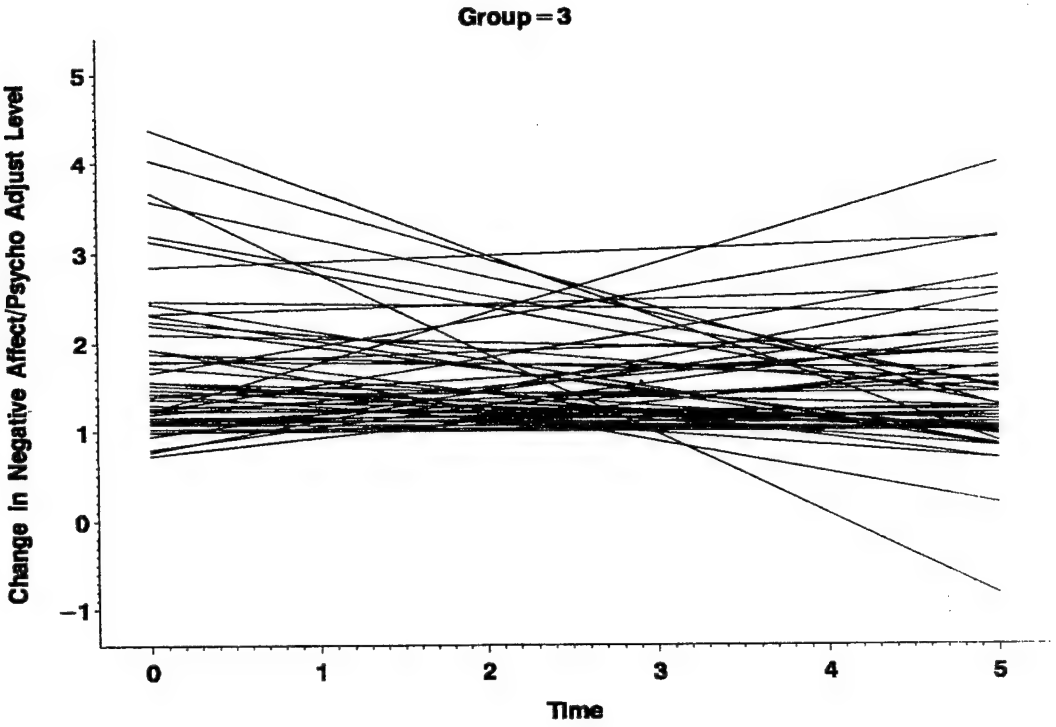
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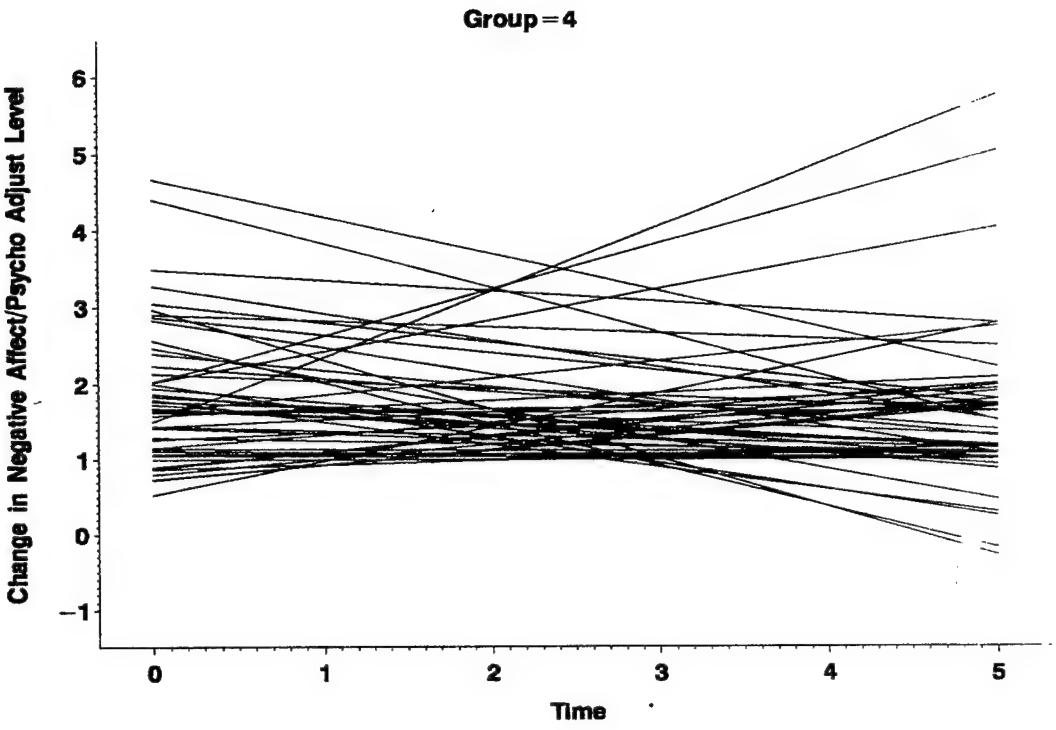
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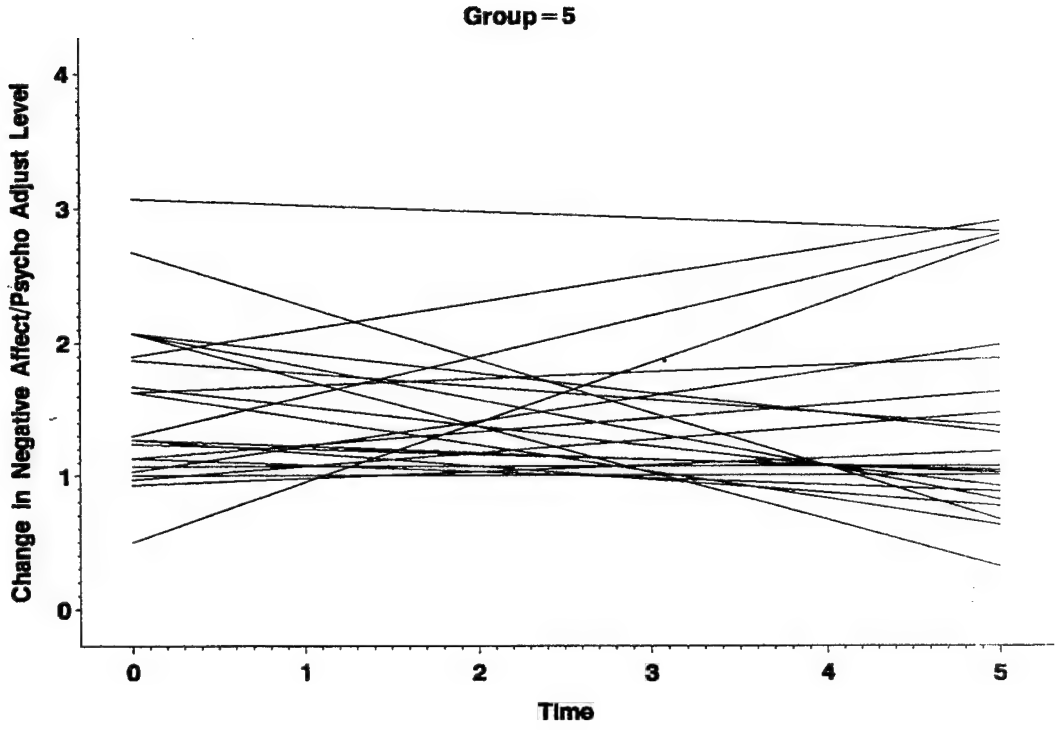
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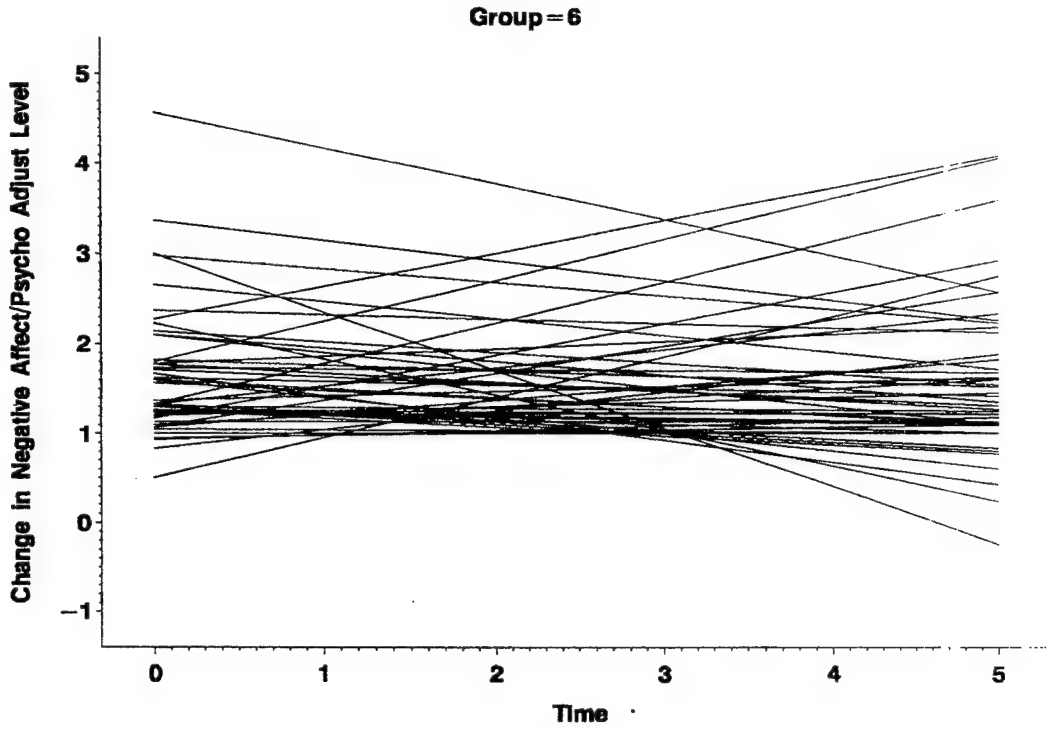
Time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Change in Negative Affect/Psycho Adjust Level
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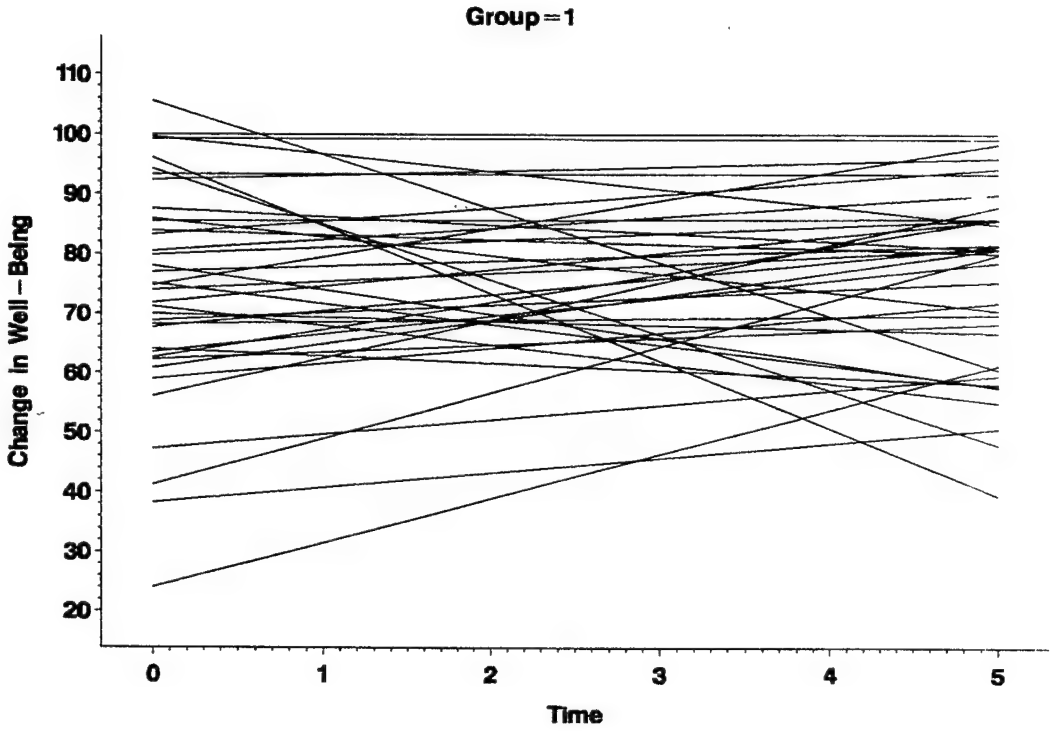
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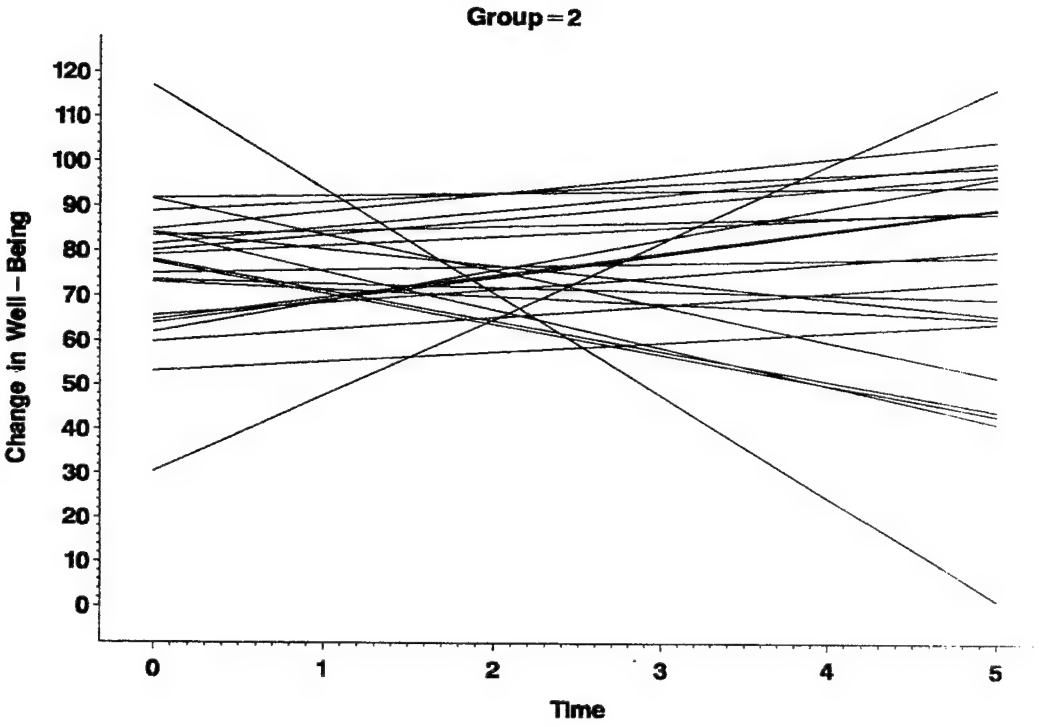
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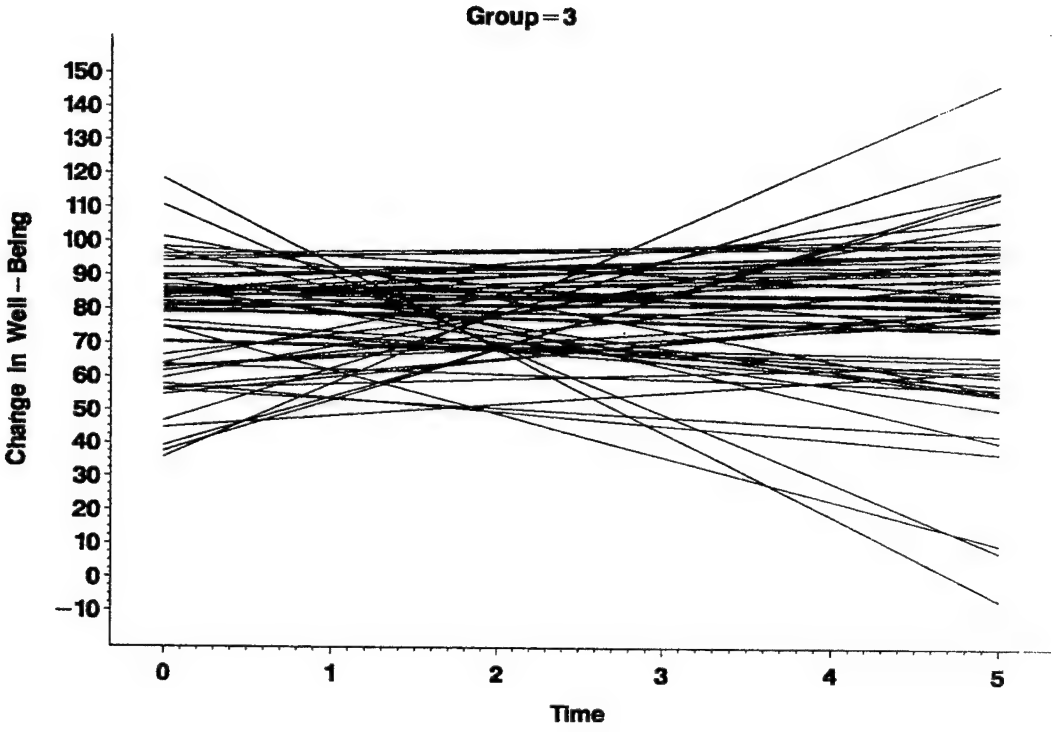
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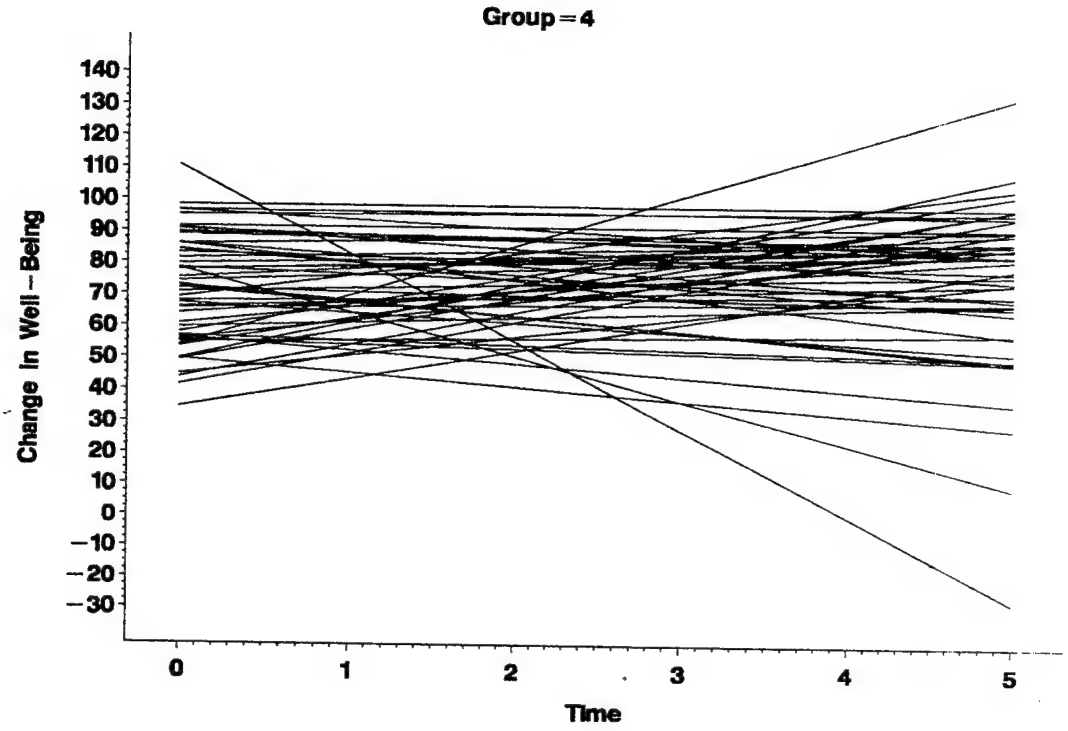
Time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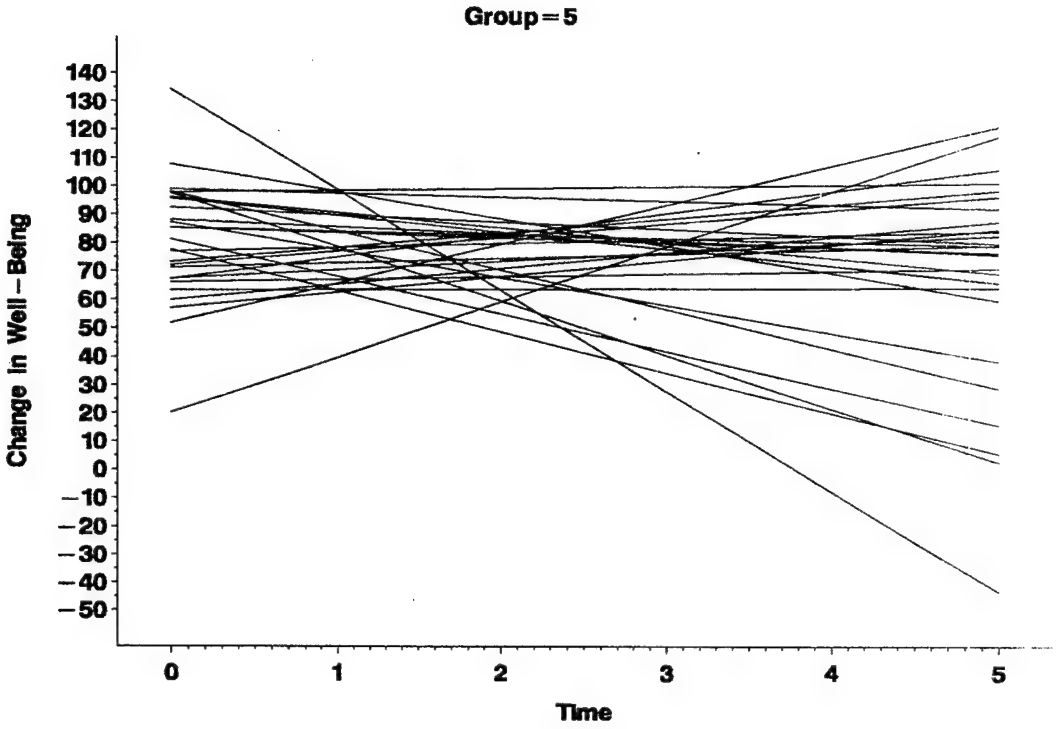
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Change in Well-Being
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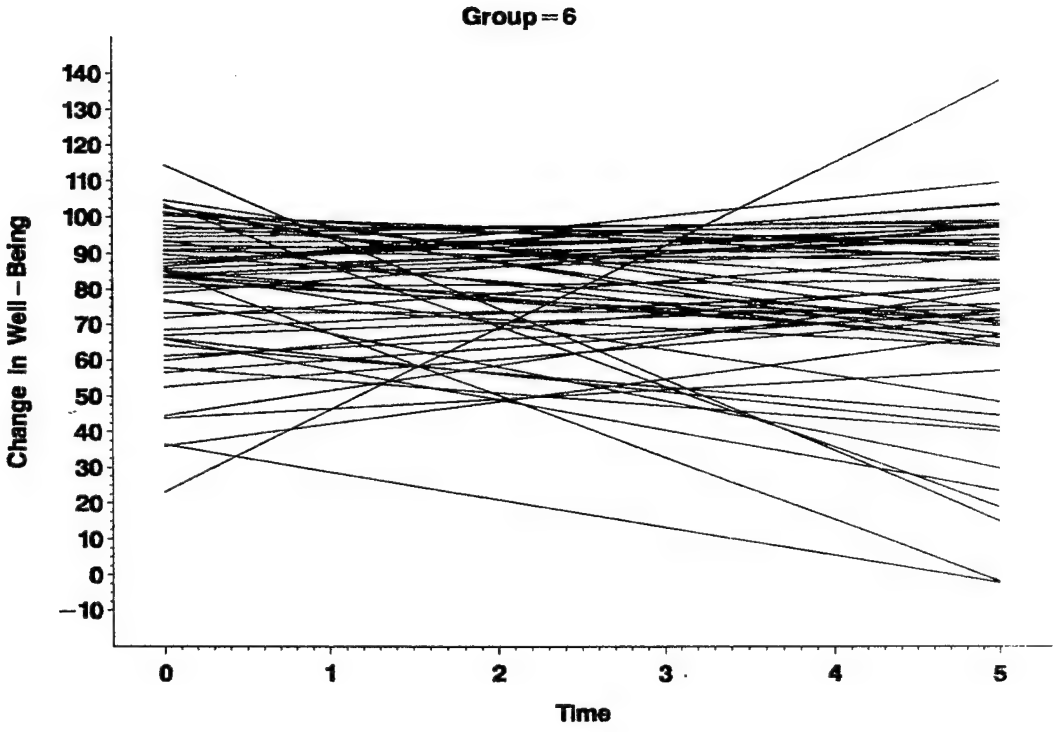
Group = 6
Change In Well-Being
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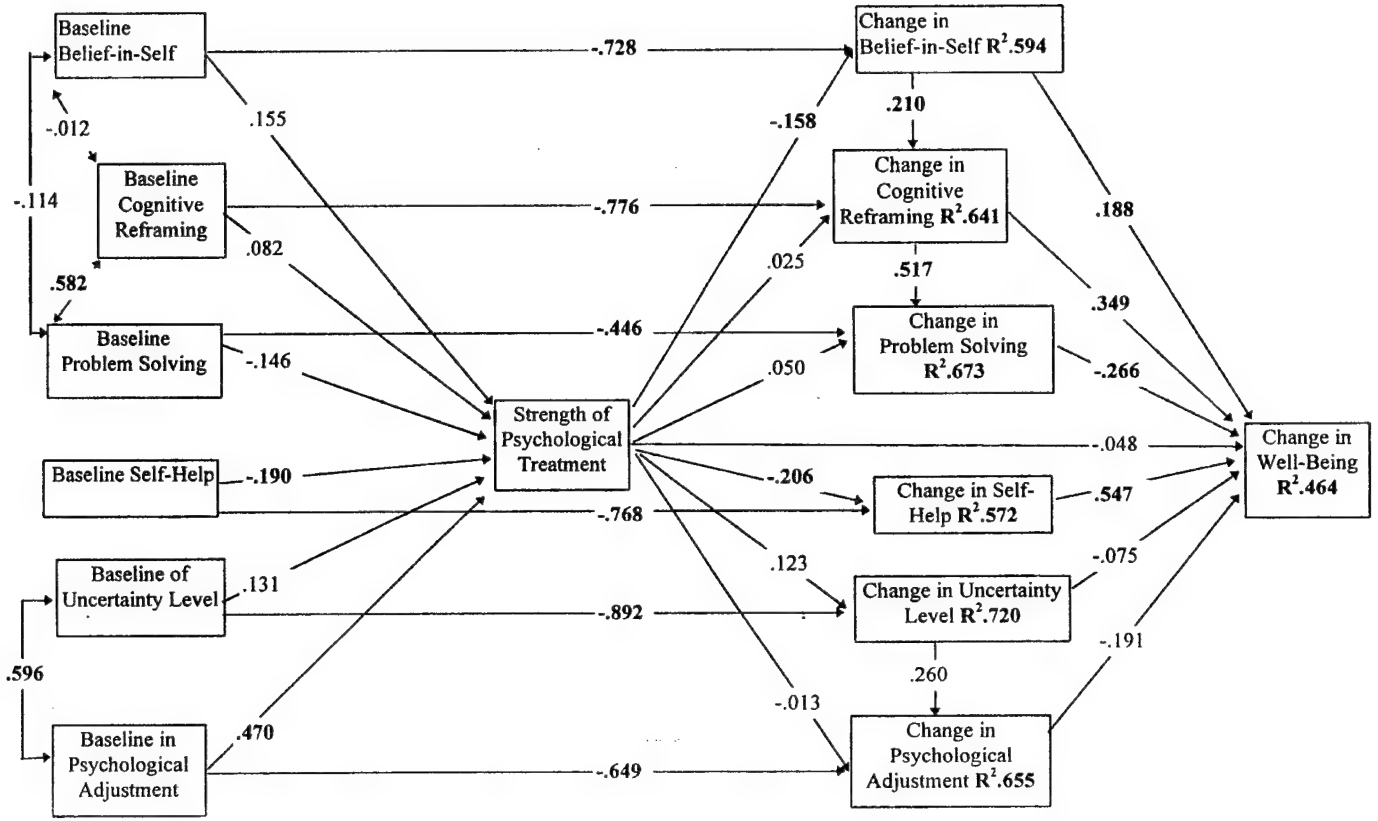
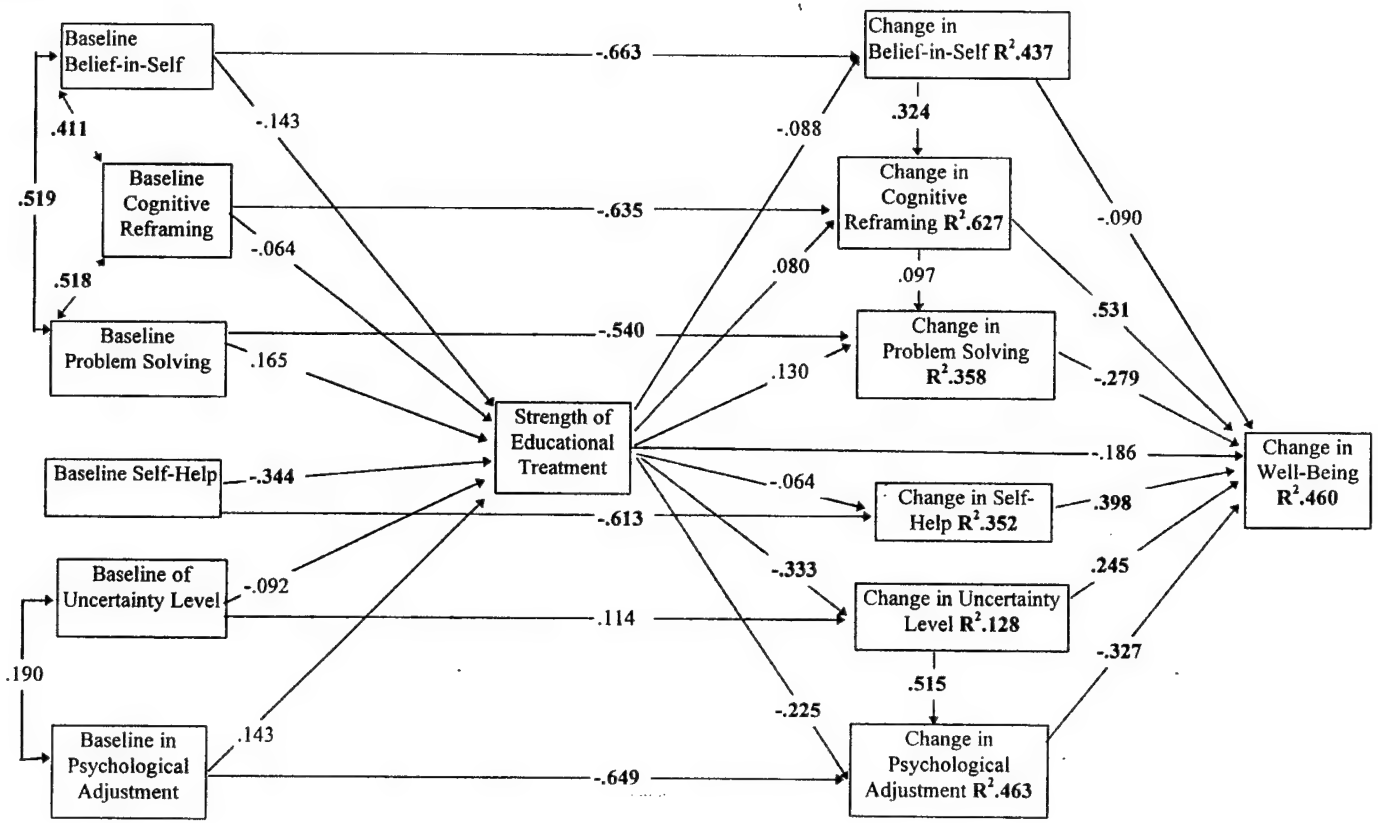
Time

UM GROUP



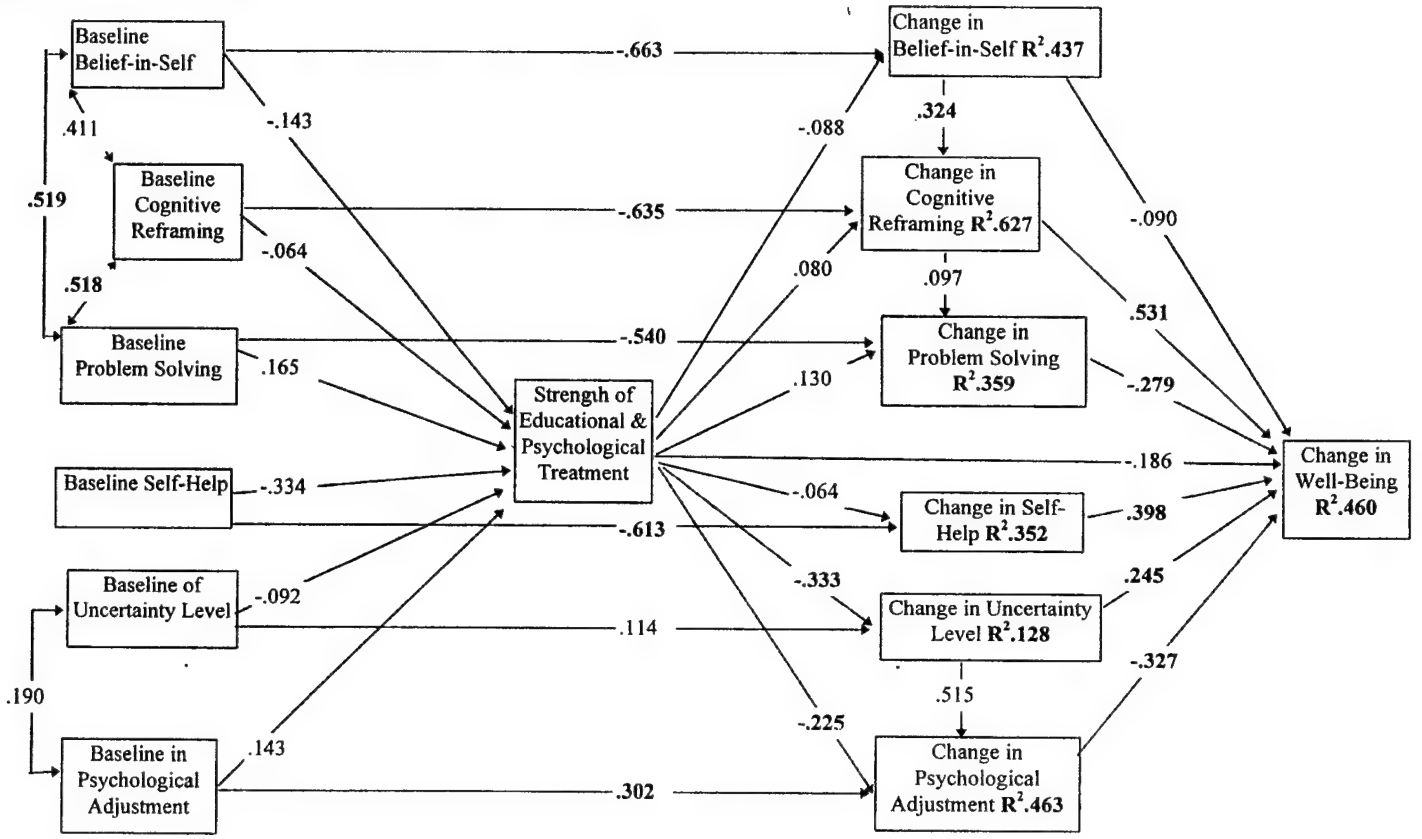
Independent $\lambda^2_{(df91)}$ =604.64, Model $\lambda^2_{(df59)}$ =165.141, CFI = .793

SHC and SHIS GROUP



Independent $\lambda^2_{(df91)}$ =291.97, Model $\lambda^2_{(df59)}$ =126.144, CFI = .666

SHIS/UM and SHC/UM



Independent $\lambda^2_{(df91)}$ =432.98, Model $\lambda^2_{(df59)}$ =112.83, CFI = .843

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